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RECENT TRENDS IN DUBIOUS AND QUACK MEDICAL DEVICES

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JOINT HEARING

TTEE ON REGULATION, BUSINESS
RTUNITIES, AND ENERGY
OF THE
TEE ON SMALL BUSINESS
AND THE
SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE
OF THE
SELECT COMMITTEE ON AGING
HOUSE OF REPRESENTATIVES
ONE HUNDRED SECOND CONGRESS
SECOND SESSION

WASHINGTON, DC, APRIL 9, 1992

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RECENT TRENDS IN DUBIOUS AND QUACK MEDICAL DEVICES

THURSDAY, APRIL 9, 1992

House of Representatives,
Subcommittee on Regulation, Business Opportunities, and Energy, Committee on Small Business, joint with Subcommittee on Health and Long-Term Care, Select Committee on Aging,
Washington, DC.

The subcommittees met in joint session, pursuant to notice, at 9:38 a.m., in room 2359–A, Rayburn House Office Building, Hon. Ron Wyden (chairman of the Subcommittee on Regulation, Business Opportunities and Energy) and Hon. Edward R. Roybal (chairman of the Subcommittee on Health and Long-Term Care) presiding.

Chairman Wyden. The subcommittee will come to order.

Today, the Small Business Subcommittee on Regulation, Business Opportunities, and Energy joins the Aging Subcommittee on Health and Long-Term Care to examine the rising tide of untested, dubious, and patently fraudulent medical devices that are marketed to vulnerable American consumers.

We are most concerned with the sometimes devastating impact that the latest brands of "snake oil" have on our senior citizens. Specifically, the subcommittees' investigation has found that health care fraud is a mushrooming, high-growth industry, expected to cost this Nation $70 billion this year, and as much as $100 billion by 1995.

One out of every 10 health care dollars now ends up in the pocket of a quack, a cheating health care professional, or with the maker of a dubious drug or device.

By 1995, the health care fraud tab will be greater than the total take of organized crime, and there are trends at work that could propel it significantly higher.

During the 1980's, the evidence shows that health care fraud grew at an astounding rate. The Pepper report was issued 8 years ago by the late chairman of the Aging Committee, the distinguished Claude Pepper, and Representative Pepper concluded that $10 billion was the annual loss due to quackery perpetrated in hundreds of clinics throughout the United States and Mexico. The Pepper report said then that rooting out health care fraud was a low priority, and today, there is little to contradict that conclusion.

Now, there are a number of specific reasons why health care fraud is growing at such a horrific rate, and the Chair will outline just a few of them.

First, it's clear that the crooks have gotten greedier, and they have gotten smarter. They circumvent Federal drug laws by inferring unfounded medication-like effects for products marketed as nutritional supplements. They write promotional brochures for electronic "black boxes" in words steeped in legal art so that they can claim, in writing, that these products have no human medical use, and then they can go out and pitch them verbally as cancer cures to individual patients.

The Chair would just like to briefly demonstrate to our colleagues an example. This box here is called a "Sweep Pulse Resonator." The subcommittee got this from the Idaho Attorney General. It was seized in a raid on a clinic in Twin Falls. The box was promoted by its inventor as a device which would cure just about anything—cancer, arthritis, or AIDS.

The way it works is that a little bottle of water and alcohol would go into this hole, this hole that's very prominent on the device. The practitioner then connects the patient to the box via an electronic "lead." Patient information was then fed into the box and the patient was told that somehow this would "electronically calibrate" and "charge" the solution of water and alcohol.

The patient would drink the solution over a period of time, or rub it on their skin. Once the medication was used up, the patient didn't even have to go back to the clinic for in-person treatments on the machine to obtain this, a magical cure. All the patient had to do was send in a personal photo, have it placed it in the machine's crevice along with the solution, and the so-called charger would do the rest.

The FDA never bothered to go after this particular practitioner. Even though these devices were being sold across this country by as much as $2,000 each. The Idaho State authorities finally went after and prosecuted the clinic. When they did, they found about 200 of these devices.

Now, Federal fraud investigators from several agencies have told the subcommittee that there are a number of forces at work that are driving the health fraud menace. First, while we know that most doctors are honest, too many have overcharged for procedures or billed for services never rendered. Quack device manufacturers are promoting and marketing electronic cures for cancer or AIDS. Some distributors of legitimate medical and health equipment sucker unsuspecting consumers to buy unneeded supplies.

Second, the scam artists move very quickly to escape investigation and charges. Very often they work out of mobile laboratories or clinics. They operate practices in several States so that a scam kingpin can jump from one jurisdiction to another just ahead of the law.

Third, prosecution of these cases for financially strapped State authorities is expensive and uncertain. The subcommittee has learned that some jurisdictions won't take a case involving a loss of less than $200,000, so that a cheat can skip town or simply change their modus operandi.

Fourth, the subcommittee has received evidence that insurance companies have been unwilling to share practitioner billing information and, as a result, insurance reimbursement fraud is perpetrated on a broad scale.

Finally, direct mail promotions and 900 number telemarketing campaigns gin-up this torrent of these snake oil products and sales.

The fact is that charlatans are using state-of-the-art technology and a new wave of marketing ploys to ply their trade. While the Government seems to be in the regulatory Dark Ages, the crooks take advantage of poor coordination between the Federal agencies and their State counterparts, the gaps between jurisdictions, and the general sense that health care fraud is not a priority.

Even though the Food and Drug Administration has told the subcommittee that health fraud is "alive and thriving," to use their words, our Federal watchdogs do not seem to have the same level of vigor.

Enforcement agencies and insurers must develop a new coordinated game plan to fight this fraud by sharing information, techniques, and even personnel, or the more sophisticated scams are going to grow. Without this strategy, more and more Americans are going to be ripped off, they're going to be demeaned, and, in some cases, driven to an early death by health fraud privateers.

This coordinated strategy has to focus on a way to cut through the electronic blizzard of claims that are now filed in a computer age. The subcommittee estimates that as many as 4 billion separate pieces of billing information are processed each year, creating new opportunities for fraud. The traditional paper trail that investigators have followed for years has been lost, and now the fraud investigators have fewer documented tracks to follow.

The subcommittee's investigation into outpatient health care shows that the lack of peer review and established standards creates a fertile field for the quacks and cheaters.

Finally, the Chair would observe that as this country debates health care reform, the Government ought to make it very clear that before citizens are taxed one penny more for health care, the Federal Government ought to make sure that the more than $800 billion that is now being spent is well spent.

Sheri Spencer, one of our witnesses today, will say, in describing her family's fatal experience with health care snake oil, "No family should have to go through what my family has." No Government ought to wink and nod at fraud which rips off and even kills consumers. Fraud investigations and enforcement efforts in the health care area are dangerously inadequate, and these subcommittees are going to work to set in place a new, stronger system that can turn this insidious problem around.

We have excellent witnesses today, and there is great bipartisan interest, as has been the tradition in these subcommittees, in tackling these issues.

[Chairman Wyden's statement may be found in the appendix.]

Chairman **Wyden**. I want to recognize the ranking minority member of the regulation subcommittee, Congresswoman Meyers, who has a track record of being involved in these issues going back to her days in the Kansas legislature. I want to recognize her for her statement.

Mrs. MEYERS. Thank you, Mr. Chairman.

Again I'm pleased that our two subcommittees are once again joining forces to tackle what appears to be a growing problem—the peddling of fraudulent medical devices.

What the late Chairman Pepper reported as a $10-billion problem in 1984 has now grown much larger, estimated by some health policy experts at $80 billion. Unfortunately, the elderly are particular targets of quack devices or procedures, as they desperately attempt to cope with the chronic health problems that all too frequently accompany advanced years, and because sometimes the elderly are isolated and lonely, and, therefore, vulnerable.

I look forward to the testimony of our witnesses today, to learn more about the variety of health care scams in existence and what can be done to help prevent citizens from falling victim to medical quackery. I would like to extend a special welcome to one of our witnesses, Dr. John Renner, who has traveled from the greater Kansas City area to be with us today.

While the solution to this may be as complex as the problem, a combination of stronger laws at the State and Federal level and more consumer education should certainly be considered. Unfortunately, the old adage "if it sounds too good to be true, it probably is" stills holds true when it comes to miracle cures for many of the tragic diseases that afflict our society.

I thank you once again, Mr. Chairman, for calling this hearing.

Chairman WYDEN. Thank you, Congresswoman Meyers.

Let me recognize our colleagues. I will recognize Congressman Lancaster and then Congressman Skelton. Both are Members who have been very involved in this fraud effort.

Congressman Lancaster.

Mr. LANCASTER. Thank you, Mr. Chairman, and thank you and Mrs. Meyers for scheduling this hearing. It is an important hearing.

Just as in the Bible it says that the poor will always be with us, it appears that quacks will always be with us, too. But just because they will be an ever-present danger to the most vulnerable and the saddest cases in our country, that doesn't mean that we shouldn't be ever-vigilant to eliminate this quackery from the health care system.

The FDA, in their statement this morning, will say that the best way to attack quackery is by public exposure. Well, I agree that public exposure is an important factor, but I think that FDA simply needs to do their job. They haven't been doing their job, and I hope that this hearing will not only focus public attention on the quack, but will also focus attention on FDA and their lack of vigilance in rooting out quackery wherever it exists. I look forward to the hearing.

Thank you.

Chairman WYDEN. Let me recognize our colleague, Congressman Skelton, a very active member of the Aging Committee and someone who's got a long track record of going after and trying to prosecute these kinds of frauds. He is a real expert in this field, and I want to recognize my friend, Ike Skelton.

Mr. SKELTON. Thank you very much. I compliment the chairman for your diligence in ferreting out this type of problem.

Not so long ago you held an excellent hearing on credit card fraud. I might add that, as a result of that hearing, I was able to spot a scam when a telephone call came to our house and my wife was told that she had won a great prize, and all she had to do was tell the person who telephoned what our credit card number was. Of course, she spotted that and asked them for some information, after which they promptly hung up. This hearing is a continuation of your antifraud efforts, and I compliment you for this.

What really bothers me is that the people who are victimized are at the lowest point in their lives, or their family is at its lowest point. They are reaching out for help, any kind of help, something that will save them or make them more healthy. They are the most vulnerable. How very, very sad this is.

It is also sad that the Federal agencies have not pursued this as they should. I think, as a result of this hearing, they will probably take renewed interest and effort, Mr. Chairman, in what they ought to do.

I remember many, many years ago, when I was a prosecuting attorney, the elderly were being preyed upon by being sold numerous lightning rods. Scams have now become more sophisticated, and the elderly, the sick, those who need hope of some sort, are being sold quackery items such as the box you displayed. So, I compliment you and let's get on with it.

Chairman WYDEN. I thank my colleague. I remember being out in Missouri with him for an Aging Committee hearing, and his longstanding interest in this area. I look forward very much to working with our friend, Ike Skelton.

We also have another dedicated member of the House Aging Committee here, Congressman Stallings, who I've had a chance to work with on a number of issues. He, too, has been very active in health care and aging concerns.

I want to recognize him for his opening statement at this time.

Mr. STALLINGS. Thank you, Mr. Chairman. I'll be brief.

I would just like to welcome a constituent of mine, Mrs. Spencer, who is at the table and who you will be hearing from. I'm sure you will be most impressed with the story that she has to tell.

This hearing is extremely appropriate, given the pressures on health care costs and the concerns that the American people have about where their health care dollars are going. If we're wasting $80 billion a year on nonsense, when we have literally millions of people who can't afford any health care coverage, there is definitely a need for Government oversight.

I appreciate this hearing, and I hope that the information we garner from this and other hearings will help us craft legislation that will help Americans get the programs and the health care that they need and deserve, rather than what some con artist is trying to sell them.

Mr. Chairman, thank you for inviting some very capable witnesses from Idaho to participate in this hearing. I look forward to their testimonies.

Chairman WYDEN. I thank my colleague. I think he touches on a point that I feel very strongly about. Before you take another penny from citizens on health care, you ought to root out the fraud. The gentleman makes a very important point.

Let me also ask unanimous consent to enter into the record at this point the statement of the Honorable Ed Roybal, chairman of the Select Committee on Aging, and also the chairman of the Aging Subcommittee on Health and Long-Term Care.

Chairman Roybal has worked tirelessly on these issues over many, many years. He is retiring this year. I feel a loss of both a professional colleague and a personal friend, one who has given many, many hours and tremendous service to the cause of senior citizens over the years. Let us, Mr. Recorder, have Chairman Roybal's statement entered into the record at this point, as well as statements from Congressmen Matthew J. Rinaldo and Ralph Regula.

[Chairman Roybal's statement with news release, and the statements of Messrs. Rinaldo and Regula may be found in the appendix.]

Chairman **Wyden**. We have another one of our colleagues who has joined us, Mr. Gilchrest. We appreciate his being here.

Would you like to make an opening statement at this time?

Mr. **Gilchrest**. Mr. Chairman, I apologize for being late. I look forward to hearing the testimony and using that information so that we can make regulations that are much more beneficial than they are right now. Thank you.

Chairman **Wyden**. I thank the gentleman. I know the gentleman has had a real interest in the concerns of senior citizens as well, and I thank him for his attendance.

Let me go to our first panel now, Mrs. Spencer, Mr. Robert Read, and Mr. Randall Everitt. I think the subcommittee has indicated to you that we swear all our witnesses who come before the Subcommittee on Regulation, Business Opportunities and Energy. Do any of you have any objection to being sworn as a witness this morning?

If you would then please rise and raise your right hand.

[Witnesses sworn.]

We thank all of you for your assistance and cooperation. We're going to make your prepared remarks a part of the hearing record in their entirety. You feel free to proceed as you like.

Mrs. Spencer, we really welcome you. I always have a certain kind of special interest in having folks come from the Pacific Northwest, and Richard Stallings made mention of the fact that you're his constituent, but you're our neighbor as well. We welcome you and appreciate your courage in speaking out.

Please proceed as you see fit.

TESTIMONY OF SHERI SPENCER, LICENSED PRACTICAL NURSE

Mrs. **Spencer**. Mr. Chairman, thank you for the opportunity to address you this morning on the issue of dubious medical devices and how they are used.

My name is Sheri Spencer. I am a wife and working mother of four from Boise, ID. I am a licensed practical nurse, and I work for four doctors whose help and support during the events I am about to describe has given me the courage and the strength to tell you my story.

My mother and I did not agree on the value of traditional medical therapies, but she always described her treatments to me because of my health care background.

The night of her first treatment she was quite upset and she called me because, as she put it, "I'm bleeding from every place I can." That didn't sound right to me, and I encouraged her to go to an emergency room at the hospital. Instead, she called Dr. Rapsemanakis. She told me that Dr. Rapsemanakis told her it was a normal and wonderful thing because the energy was going into her system and it was "exploding" the cancer cells. He told her that the first treatment always traumatizes the system. She did not go to the emergency room.

My mother started out hooked to Dr. Rapsemanakis' machine for 1 hour a day, 4 days a week, and then a week off. He charged her $100 per session, telling her he was only charging her for the use of the space, the cost of the electricity, and for staff time. He told her he was not charging her for his time because she was his "miracle" patient, in that he had never before cured so developed a cancer.

The treatments soon expanded to 3 hours a day, 6 days a week. My mother told me she was feeling better, but her looks told a different story. I noticed when I visited with her that she had puffy and infected sores on her back where the electrodes were attached. She was rarely at home in Utah and spent long stretches of time in Las Vegas to be close to the therapy. It was also at this time that I noticed that the skin above her right eye had begun to sag.

Soon after, Dr. Rapsemanakis told my mother that he now had to treat her brain. Then he started treating her above the neck. At this time I thought my mother began acting very differently. Though she said she felt great, she had lost over 60 pounds, she was jaundiced, and she seemed confused at times.

I begged her to see another physician because I thought the cancer was spreading. At one time I had worked for a home health care agency and had taken care of terminally ill patients. She told me that Dr. Rapsemanakis told her that the cancer was now gone but that curing her had taken a toll on her body and soon they would begin treatments to rebuild her body.

Mr. Chairman, my mother trusted this man and my whole family wanted her to be happy and well. My urging her to see another doctor caused great pain between us, but I didn't know what else to do. Try as I might, I could not convince her that she was getting worse, not better.

On April 19, 1991, Dr. Rapsemanakis called my mother in and told her that she was "completely cured." He told her that she didn't need to come back any more, that she could go home and spend time with her family. My mother told him she still felt and looked sick. He told her that she should be grateful that the cancer was gone, but that he couldn't do anything about how she looked.

When she came home, she told members of the family that she still felt funny and she could almost feel things "growing inside." She wanted to go back to Las Vegas for more treatments. She eventually returned to the clinic where she was told she could have four more treatments on the energy machine, but that was all. My mother was especially distressed because they wouldn't give her

I am here to tell you of my family's experience with a questionable medical device and the tragedy that it brought into our lives. I am also here in hopes that something more can be done to ensure that what happened to my family does not happen to others.

Last June, my mother died of cancer. She was 54 years old, and she left behind a husband, nine children, the youngest of whom was only 13 years old, and 15 grandchildren who all miss her and love her very much. I am convinced that the treatment that my mother received from an untested and unproven medical machine contributed to both her failure to seek proper treatment and ultimately to her death. This is her story.

In March 1990, my mother was diagnosed with a lump in her left breast. My mother had always been suspicious of doctors but agreed to have the lump surgically removed at a hospital near her hometown of Orem, UT. Prior to her surgery, my mother had been in contact with a medical doctor who practiced various forms of alternative cancer therapies. He told my mother to make sure that the surgeon remove and preserve the lump for further investigation and to make sure that the surgeon did not remove any of the surrounding tissue.

The operating surgeon found a tumor the size of a grapefruit, and he also found that the cancer had metastasized into the surrounding tissue. Nevertheless, my mother rejected his treatment recommendations and returned to her alternative therapy after signing a waiver releasing the operating surgeon from all future responsibility. The alternative therapist took the tumor and made what he called an "antiserum" from it and began my mother on a course of alternative anticancer treatments.

In September 1990, while my mother was still receiving the antiserum treatment, she met a man named Evens Rapsemanakis from Las Vegas, NV, who ran a pain clinic in Las Vegas, where he claimed he cured cancer and other diseases such as diabetes. He told my mother that he was not a medical doctor but a scientist and an inventor with a Ph.D. from a Greek university, and that he had developed a new type of energy and electrical therapy while working for the McDonald Douglas Corp.

The energy and the machine that he invented, he said, would entirely eliminate the need for medical doctors. However, when he told McDonald Douglas of his discovery, they fired him. Rapsemanakis also told my mother that the medical profession would have him killed if they knew he had a cure for cancer.

Dr. Rapsemanakis, as he called himself, told my mother than in order to treat her, she would have to have a referral from a practicing health care professional. He told her to visit a Las Vegas chiropractor who would formally refer her to his "Paradise Pain Clinic." The chiropractor told my mother that she was a prime candidate for a heart attack and referred her to the clinic.

My mother began a course of treatment at the Paradise Pain Clinic in September 1990. The treatments, as I understand them, consisted of hooking her up to a machine that generated low-current electricity by means of electrodes hooked directly to various points of her body as she sat in a reclining chair.

the full 3 hours of treatment. Dr. Rapsemanakis said that he had too many other patients who needed his help.

When she came home, she continued to feel and look bad. Finally, the family demanded that she get a CT scan, if for no other reason than to prove the cancer was gone. The CT scan found that she had a tumor in her skull above the eye that was sagging. She had another tumor the size of a golf ball behind the opposite eye. She had multiple tumors in her breasts and the femur bones in her legs were so full of tumors that they were mottled. The oncologist who analyzed the CT scan told us that there was no hope to reverse the cancers, and after he saw her surgical record, he informed us that her cancer was treatable at the time of her original surgery.

My mother soon lost the ability to walk and to talk. In the first week of June 1991, Dr. Rapsemanakis called to see how my mother was doing. My mother still trusted him, but I was furious. My mother could no longer speak, so I talked to him. I told him the cancer was everywhere and that he had done nothing for her. He told me that he had cured her and that the cancer might show up on the x ray, but that it was dead. He wanted me to put her back on a special diet and to bring her back to the clinic so that he could start a "rejuvenation phase." I told him that I would never let her set foot in there again, and I hung up on him.

My mother died of cancer on June 25, 1991.

I was very angry, but I didn't know what to do. The doctors I worked with told me to call the Nevada and Las Vegas Medical Societies. I tried that, but nobody knew who I should report to, and in one case the phones were disconnected. Finally, one of the doctors in my office put me in touch with a Dr. William Jarvis in California, who is a well-known expert on medical quackery. Dr. Jarvis put the FDA in touch with me, and, in fact, 2 weeks ago, I was extensively interviewed by the FDA about this experience. I have been told that the Paradise Pain Clinic has been shut down, but Dr. Rapsemanakis is still out there and, for all I know, he can still continue to "cure" people with his machine.

Mr. Chairman, I am here today because no family should have to go through what my family did. Even today, we do not all agree. Some in my family are grateful to Dr. Rapsemanakis because they don't think my mother was in any pain when she died. I am not quite sure. This has been hard on all of us, but it has brought us closer together as a family. We are getting better.

In closing, I would like to say that I've thought about why my mother fell under this man's spell. Traditional medicine isn't perfect, and their machines and treatments don't always work, either. But I think my mother saw this as a course of treatment and a way to control her medical destiny. I also think that for the time that my mother was Dr. Rapsemanakis' "miracle patient," he treated her with a special care and gave her hope that she did not find in traditional treatments. I hope that traditional doctors and those working on legitimate alternative therapies might learn something from the fear and isolation that caused my mother to reject their help. I hope you on these subcommittees will find ways to ensure that my mother's story is not repeated in another family.

Thank you for allowing me to tell my story.

[Mrs. Spencer's statement may be found in the appendix.]

Chairman **Wyden**. Thank you very much, Mrs. Spencer. We very much appreciate your courage and your willingness to speak out. No one who hears a story like yours, or hears from a family member, can really identify with just how tough it is to come forward and to speak out as you have. I think you put the call to arms very well. It's the job of the Congress to hear that call and make sure that families across this country don't have to go through what yours has.

We will have some questions in a moment, but I just want to thank you for a very, very helpful statement. You said it a whole lot better than a dozen Government reports or experts or so-called theoreticians of the health care field could do. We appreciate it.

Mr. Read, before we go to your testimony, one of our colleagues, Dave Camp, has joined us. He, too, has had a long-standing interest in these issues, and I want to give him an opportunity to make an opening statement at this point.

Mr. **Camp**. Thank you, Mr. Chairman. I don't have any statement at this time. I want to listen intently to the testimony, and I also want to commend Mrs. Spencer for what must have been very difficult. You do show a lot of courage.

Chairman **Wyden**. I thank my colleague.

Mr. Read, welcome.

TESTIMONY OF ROBERT B. READ, PRODUCER, INSIDE EDITION

Mr. **Read**. Thank you, Mr. Chairman, and members of the committee. My name is Robert B. Read, and I'm a producer for the television news magazine program "Inside Edition."

I am not in the habit of appearing before Government bodies, but when I was requested by the staff to appear this morning to highlight one of our investigations, given the public safety issues involved, my colleagues and I decided it was appropriate for me to appear.

Over the years, I have reported on numerous cases of medical negligence, questionable treatments, and sometimes outright quackery. Although the potential for physical harm and/or financial loss existed in all of these cases, most were relatively isolated situations, their reach limited to the particular locale or community.

But when reporter Steve Wilson and I began to looking into the Century Clinic in Reno, NV last year, we were amazed at the far-reaching effects of this one medical practice. We found the large waiting room filled with patients, many elderly, some from as far away as Maine and Hawaii, and they were being treated for everything from alcohol abuse to artery disease and multiple sclerosis.

Many of the patients swore that this clinic was their only hope, that doctors here could do what none had been able to do before. But we also heard from a woman in New Jersey, whose diabetic husband died after visiting the clinic. She says they took him off his insulin in favor of their own treatment. One of our viewers from Nevada, who you will see in a moment, told us that she and her daughter were misdiagnosed and dangerously mistreated there.

To see if these charges were true, I decided to make an appointment and visit the clinic myself as a patient. Although the initial exam seemed quite normal, I soon encountered devices and treatments that I had never seen before.

With the committees indulgence, I would like to show a shortened version of the "Inside Edition" report which was originally broadcast on November 1, 1991.

Chairman **Wyden**. We'll have the staff get the lights, and we'll view the film.

[Video Presentation.]

Chairman **Wyden**. That was very instructive, Mr. Read. Go ahead.

Mr. **Read**. Thank you. Just a final note.

We phoned the clinic yesterday and were told to come on down for an appointment, which would include an electro-diagnostic exam, so it appears that it's still business as usual at the Century Clinic.

Chairman **Wyden**. I'm sorry, I want to make sure I understand this.

You're saying that the clinic we just saw on the screen is still operating in the same manner, and, as far as you know, it's just business as usual?

Mr. **Read**. It appears so, based on the phone call. We weren't there yesterday, but we made a phone call to make an appointment, and they did say the electronic diagnosis was included.

[Mr. Read's statement and text of the video, may be found in the appendix.]

Chairman **Wyden**. Mr. Read, that was very helpful, and I know we're going to have some questions for you in a moment.

Mr. Everitt, welcome. We know of your good work out in the Northwest as well. Please proceed.

TESTIMONY OF RANDALL EVERITT, CRIMINAL INVESTIGATOR, OFFICE OF THE ATTORNEY GENERAL, STATE OF IDAHO

Mr. **Everitt**. Thank you, Mr. Chairman.

I am a criminal investigator with the Idaho Attorney General's Office. I primarily specialize in homicide cases. Originally, when the devices that you see before you came into our control, we were initially investigating a potential homicide case. We had received information through the Board of Medicine in Idaho that a purported physician in Twin Falls, ID was treating people for various diseases, such as cancer, AIDS, and leukemia. We had a patient out of New Mexico that purportedly had contracted cancer of the throat, and his physician who had examined him was outraged by the story that this patient had told.

What we found out through our investigation was that a Mr. Arbaugh had gone to Twin Falls after having been diagnosed as having cancer, was treated by a purported naturopathic physician, Dr. Solomon, and for a period of 3 months received various electronic therapies, as well as tinctures. He reported back to his physician in New Mexico that things weren't getting much better, and, hence, we became involved.

As a result of our investigation, along with the local FDA in Idaho and Seattle, we gathered information and seized approximately 200 devices, a sample of which you see here in front of you, in eight separate search warrants over a 24-hour period of time.

I will admit that when I became involved in this investigation, I didn't know very much about health fraud. I knew about homicides. I knew how to conduct certain types of other investigations. But as I entered the clinic in Twin Falls, and the secret laboratory, and the manufacturing and distribution house in Buhl, ID, I was appalled at the types of devices and the way that these things were being treated. I was appalled at the number of patients who had come under the purview of these types of individuals, particularly Dr. Solomon. As a result of this investigation, we seized, as you see before you, a random sampling.

I would like to describe them to you in more detail, if I might, and show you how they work, and show you what they were purported to do, with your permission.

Chairman WYDEN. If the staff could move that microphone, I want to be sure the Members can hear. Thank you.

Mr. EVERITT. What you see here is a sampling. The grandfather of these devices would be basically the machine that comes out of England. This is an electronic device which was seized in the Solomon clinic. You will see two metal plates on top of this machine and a number of dials and a switch.

What we found is a secret clinic where Solomon was employing a number of people to take tinctures of various water and alcohol, place them on a metal plate, tune in the dials, and there would be a rating or an electrical charge that would be emitted into these vials. These were the curative effects or the remedies that he would market throughout the United States. We found that these devices here on this table were being distributed to 13 other States here in the United States, as well as two foreign countries. We found files of patients from 38 States throughout the United States. We found photographs of different victims, patients, if you will, of Dr. Solomon.

What we have decided is that we would turn this particular investigation, at least for the national impact of it, over to the Food and Drug Administration to work on the other distributors of these devices. This device here is, as the Congressman said, a sweep resonator. You put a photograph of your loved one or a friend in the well. A device such as this runs about $950.

This device right here is a Super Pro. I was particularly impressed with this device, because if you would like to sit in a chair, like you will see most of the patients in the earlier television broadcast, you will see in the Solomon clinic where patients would be sitting in easy chairs, such as you saw before, sit with their feet on these plates, turn on the Super Pro device, and the plates would draw toxins and poisons through the system on to the plates and have a curative effect.

Also, if you were to sit at home and watch television, you could purchase one of these devices, a little resonator that costs about $350. That would take out all of the harmful energy being emitted by your television set, your radio, microwave, that causes various types of diseases.

The one I particularly like the most is this one. This one is the J. SOLTEC device, standing for James Solomon Technology. This device can be tuned to a certain position and with this wand, you hold it over various parts of your body and the waves that are purportedly emitted from this kill certain types of bacteria, will help cure cancer, AIDS, and leukemia. We have a list in here that runs from A to Z.

This device here runs retail about $1,600. It's a portable device, and when you go into Mr. Solomon's clinic, you can sit down and be treated there for a period of a 1 or 2 months, buy the device, take it home with you, and treat yourself.

One of the things I would like to read to you is the level of technology that went into this type of machine. "All shipments of FG7 from this date will be called SOLTEC. We will be changing the 4 and 5 frequencies which grow cancer to 1,482 and 1,901, which arrest cancer growth."

We have a video film in our files right now where Solomon, as well as the manufacturer of the devices, are attending a convention in Denver. They told all of their people "you've got to be careful with this device here, because this one frequency grows cancer. Do not use that frequency any more. Go to this other frequency or, better still, buy this new device."

We've seen a lot of built-in obsolescence as these things come along. These are fourth, fifth, and sixth generation devices. They are being manufactured and distributed throughout the United States.

In Idaho, we take a very dim view on this kind of activity. The attorney general of our State is enraged by this type of quackery. We will pursue this kind of quackery in our State. But, sir, we are lost when we go outside the State of Idaho. We need the help of the Federal Government, the Food and Drug Administration, to continue on the kind of investigations that we have.

One other thing I would like to say before I sit down. If you all thought that your children were safe going to school with immunizations that they have from the Public Health Service or from your family physician, you can also be immunized by various tinctures and sugar pills that we seized from Dr. Solomon. That includes immunizations for polio, scarlet fever, small pox, typhoid, mumps, chicken pox, red/black/yellow measles, diphtheria, tetanus, and meningitis.

As you can see, all of these devices are fraudulent. All of these devices, when tested by the Food and Drug Administration, have no medical curative effect. We have a warehouse in Boise full of these devices that we seized through Dr. Solomon's office, the Bouchet Enterprise that manufactured them, and the clandestine laboratory that made the tinctures and remedies.

In closing, Mr. Chairman, the State of Idaho is probably no different than any other State out there. We have jurisdictional problems clear across the board. We can't go to North Carolina, Michigan, and Florida, to track the distributors of these devices down. We know where these devices were manufactured. They were manufactured in our State. We've got them. But I know very well that those devices right there have patents on them. Those patents have been sold to other manufacturers, and they are being manufactured again and again out there. We can't go after them. I would like to, but I think the FDA can.

Thank you.

[Mr. Everitt's statement may be found in the appendix.]

Chairman WYDEN. Mr. Everitt, thank you for an excellent presentation. I think you make a very compelling case that the Federal Government has got to be a better partner in fighting these frauds. I'm working on legislation that I'm going to introduce shortly that will allow State attorney's general to go into Federal court to enforce some of the consumer protection remedies against phone-scam-artists and to go after some of the people who skip from jurisdiction to jurisdiction, run national programs, and make it tough for State investigators to pursue them. But, we must look for additional solutions.

I will have some questions for you in a moment, but I want to let my colleagues begin the questioning. Congresswoman Meyers will start the questioning for the committee, but I see Congresswoman Bentley has come in. She has a longstanding record as well on the Aging Committee. Let me recognize her first if she would like to make a statement at this time.

Mrs. BENTLEY. Mr. Chairman, thank you. I am very interested in what has been shown here this morning and look forward to the rest of the testimony.

Chairman WYDEN. Congresswoman Meyers will begin the questioning.

Mrs. MEYERS. Thank you, Mr. Chairman.

I would like to direct a question to Mr. Everitt, if I may. Once you discovered this and decided that Dr. Solomon was perpetrating a fraud, when you prosecute, then is it a criminal prosecution?

Mr. EVERITT. Yes; it is. We prosecuted Dr. Solomon under the grand theft statute. At that time, the State of Idaho did not have adequate laws to cover the practice of medicine without a license. We do now as a result of this case.

Mrs. MEYERS. Then did Dr. Solomon go to jail? Did he actually do jail time, or was he fined? What kind of prosecution was there?

Mr. EVERITT. We elected to preserve Dr. Solomon as a witness in case any further investigative effort by the Food and Drug Administration would take place. He did plead guilty. As part of his sentencing, he will be helping us whenever we so desire. He has not gone to jail.

Mrs. MEYERS. How can we improve the Federal role in prosecution? Do we need tougher laws, do we need better kinds of exchange of information between States? What sort of thing would you suggest?

Mr. EVERITT. My suggestion would be that, if we're going to investigate these kinds of crimes and ultimately prosecute them, we do need to join in as a team. We need to work basically as a task force operation to take these people on.

Usually, these kinds of cases like that are very, very self-contained. We know, once we get a supplier and a distributor, where the tentacles go to. These can be attacked one at a time like that. But it is my understanding the Food and Drug Administration is primarily a regulatory agency. They need a good, solid investigative arm. They need to be able to go out with subpoena power and seize records and documents.

Oftentimes, from what I understand in working with the FDA, they will send letters of requests for information, or letters to some of these practitioners to cease and desist their operations. To me, that's a clear warning that that practitioner or that fraudulent doctor either moves someplace else or covers up. So, I think they need to review that kind of enforcement type of effort.

Mrs. MEYERS. Thank you, Mr. Everitt.

If I may, Mr. Chairman, I would like to direct a question to Mrs. Spencer. I appreciate your coming in and sharing your experience with us. I know it wasn't easy.

Have you arrived at any conclusion about how best to prevent this from happening again? What kinds of steps could the family have taken, or maybe the medical society? Who could you have turned to? I'm sure you must have thought about this a great deal. What advice would you give us?

Mrs. SPENCER. When the experience was taking place, I was embarrassed because of the area that I worked, to see my family so duped, if you will. So, I didn't speak out as much as I could have. I am so appreciative of this opportunity. It kind of helps me to clear my conscience, because I'm able to speak out and try to protect people from this.

I think that a great deal of the pressure to alleviate this kind of thing lies with you, because the way I look at it, we've had to make laws to have people wear seat belts because they're careless or forgetful. The people who are in this position, they're not just careless or forgetful; they are desperate. If they can hear something that they want to believe, it's going to be very hard to change their mind. I think that you need to have laws that are strong enough that will prevent these people from being able to say these kinds of things to them. You have to protect them.

Mrs. MEYERS. Thank you, Mrs. Spencer.

Finally, Mr. Read, I commend you for your work with the clinic in Las Vegas, because I think maybe education is probably the primary way that we can attack this problem, and certainly television is a powerful educator.

Do you plan to do a series, or do you plan to do any more work in this area of medical quackery?

Mr. READ. We have prior to this, and we continue, to do stories and investigative reports in this area. Many of our reports, such as this one, come from viewers. This one called us and said "I believe I've been duped and I believe I've been taken and harmed." So yes; we will, and we may even continue to update this report based on this committees findings and other developments.

Mrs. MEYERS. I thank you all very much for being with us this morning.

Thank you, Mr. Chairman.

Chairman WYDEN. I thank my colleague.

The gentleman from North Carolina.

Mr. LANCASTER. Thank you, Mr. Chairman. I thank the panel for their excellent testimony, and especially the very moving testimony of Mrs. Spencer.

Mr. Everitt, I'm a bit puzzled by the situation in Idaho and wonder if what you have turned up in Idaho exists in other States. In other words, are you simply more vigilant than other States in turning this up, or does Idaho for some reason attract this sort of quackery.

Mr. STALLINGS. Be careful.

[Laughter.]

Mr. LANCASTER. Really, I'm serious. Was it because of your lax statutes on the practice of medicine that Idaho has a warehouse full of this stuff that you confiscated, or is it likely to be found in many other States across the country?

Mr. EVERITT. Since this case, we have worked in conjunction with numerous States out West. This is not new to Idaho. It's new to Idaho for us because we have a small population base. These kinds of things stick out more in our area. This is happening everywhere. We are working with California, Washington, and Oregon on the types of medical fraud and devices that they have there. We all have the same kinds of things.

Idaho is coming of age when it comes to the enforcement of these kinds of devices. Sometimes the educational process is very slow getting to the enforcement people. I didn't know that they existed, in general terms, before 3 years ago. So, to answer your question to all of the above, yes. We get singled out sometimes because of our small population base. People seem to think that western States, because of where you're at, local law enforcement is untrained or unskilled—that's not the case usually—and we become targets for this kind of thing.

Mr. LANCASTER. I guess really the basis of my question is, do you have reason to think that these kinds of quacks are in operation in many other States?

Mr. EVERITT. Oh, yes, sir; there is absolutely no doubt about it. I can show you at least 13 States that I know of right now in this investigation alone where quacks are using not only these devices but other devices as well.

Mr. LANCASTER. That's because the seller of these sells into those 13 States?

Mr. EVERITT. That's right, sir.

Mr. LANCASTER. So, you know that this equipment is in use?

Mr. EVERITT. That's right, sir.

Mr. LANCASTER. Can you either list those 13 States for us now, or can you provide that list for the record?

Mr. EVERITT. I can provide that list for the record.

Mr. LANCASTER. But you don't know it now so that you could simply spout it out?

Mr. EVERITT. I can give you about 10 of them off the top of my head.

Mr. LANCASTER. Why don't you give us what you can, so that we can at least alert the people in those States to be on the lookout.

Mr. EVERITT. We have provided that information to the Food and Drug Administration to pass on to their field offices out there.

The States that you're the most interested in are Florida, probably one of the biggest violators, North Carolina, South Carolina, Pennsylvania, Massachusetts, New York, Nevada, California, New Mexico, and Texas.

Mr. LANCASTER. You indicated that you have passed this information on to the FDA. You also indicated that, in your opinion, what is needed is an investigative arm of the FDA.

Mr. EVERITT. Yes, sir.

Mr. LANCASTER. What has been the level of cooperation between your office and the FDA in investigating these particular cases in Idaho?

Mr. EVERITT. Sir, we've had extremely good cooperation with the FDA at the local and regional level. The Seattle district office sent many, many agents down to help go through the records with us. The device centers that review these devices for the Food and Drug Administration were very, very helpful in telling us what they were.

But as far as the continuing investigation, of taking the information that we had and pursuing other violators, it appears that that has not taken place.

Mr. LANCASTER. Do they give you a reason? Do they say the reason is lack of staff and funding, or a lack of appropriate laws to assist in that role, or is it simply a silence on their part?

Mr. EVERITT. Mostly, we don't have a reason.

Mr. LANCASTER. One of the things I found very interesting in your testimony was you talked about a convention. Are there actually conventions of quacks, where they get together and talk about how to bilk poor defenseless and vulnerable people out of their money?

Mr. EVERITT. Yes, sir; these conventions are very sophisticated in nature. It is not how can we bilk the unsuspecting and the unwary. It is, we have new devices. It's more like a trade convention, where they will take their wares, distribute them, set up booths, explain how they work, and then put out the latest technology to the other distributors of these devices. This is not a convention generally for the public——

Mr. LANCASTER. Right, but for the quacks.

Mr. EVERITT. Exactly. The one convention that I reviewed on tape, which was a tape we seized from the manufacturer here, was obviously him selling his devices. By the same token, they were asking for Federal investigators or any State investigators to stand up in the back and identify themselves. At the beginning of every one of these tapes that we saw of these conventions, they would put out the caveat "This is for experimental use only." Then they would go on to describe how these devices would cure cancer, AIDS, and leukemia.

Mr. LANCASTER. Mr. Read, I was curious about one of the things you said in your testimony. You said that you called this clinic this morning and they still want you to come back in, even after this investigative report has been broadcast?

Mr. READ. Yesterday, an associate producer of ours phoned the clinic, just to see if they were still in operation, not to make an appointment for myself.

Mr. LANCASTER. Oh. I thought you said they wanted you to come in for your treatment.

Mr. READ. No; I'm sure they wouldn't mind, but no. It was just to see if they were still in operation and if they were taking appointments. They offered the fact that they're still using this electronic diagnosis.

Mr. LANCASTER. What do these people give as their professional credentials? You called them "doctor."

Mr. READ. Well, interestingly, Dr. Tang, the gentleman, is a Harvard graduate, a Harvard Medical School graduate. His wife, Dr. Katrina Tang, is, from what we've been able to determine, a graduate of a medical school, the University of Taiwan Medical College, but does not have a licensed M.D. in any State in the United States that we can tell.

Nevada is one of the few States that has a Board of Homeopathy, a separate medical board, which has certain powers. She's a member of that, a doctor of homeopathy.

Mr. LANCASTER. Thank you very much.

Chairman WYDEN. I thank my colleague.

The gentleman from Maryland.

Mr. GILCHREST. Thank you, Mr. Chairman.

Mrs. Spencer, your testimony was eloquent, and it certainly gave us a sense of the problem that people have when they're involved in those situations. I was going to ask you a series of questions which were, from my perspective, practical questions to find out why your mother continued to pursue this medical treatment. But the way you described it showed us the human side of it and the difficulty in explaining to someone that they weren't getting the proper treatment.

Having gone through that, there are two things, I guess. First, we do need some Federal regulations so that the link between the States can be reinforced and the FDA can be a facilitator, so that there can be some reciprocity between States to get these people locked up in jail, or locked up someplace, so they can't be harming other people.

Second, having lived through that, and understanding the depth of desperation that people go to find a cure, is there any recommendation that you can make to us and to other families that might be experiencing the same kind of trauma, what they can do to help provide some sense of security to those people who are experiencing these types of diseases, so that they can—I guess what I'm saying is how can we reach them with the family, with local physicians, with local ministers, with a hospice? What type of extended family community can we create to help them?

Mrs. SPENCER. As I understand what you're asking, I think that you mean as onlookers, who see them so caught up in this, how can we be the voice of reason to them?

Mr. GILCHREST. Right.

Mrs. SPENCER. I think it's very important for people to realize that it's OK to get a second opinion, and it's OK to disagree with your health care person, whoever it is. Even if it's a renowned surgeon of some sort, you can still disagree and get a second opinion. That's our freedom. To allow these men to have ultimate power is where the danger lies.

I think education is important. I think educating the family and making things available. My mother-in-law just got diagnosed as having cancer also, and she is going a very traditional route and the prognosis is very good. We went down to the hospital, and we went to the cancer treatment center in our hometown, and we were able to find brochures, pamphlets, and things that explained what she was going through, explaining the treatment she would have. We gave those to her so that she was informed about her own disease.

I think as long as you're informed, you're in control. But when you allow another person to constantly give you the step by step, that's when you lose your control.

Mr. GILCHREST. Are there still some members in your family that feel that—I don't want to call him a doctor—that Rapsemanakis didn't do anything wrong? Are there still people in your community that feel that way?

[Witness nods.]

Mr. GILCHREST. Do you know where this man is right now?

Mrs. SPENCER. My understanding is that the FDA was able to close his clinic, but that he lives in an apartment in Las Vegas. He has sued the reporters who did the stories on him which brought this to the attention of the public. He has sued some of his patients—not my family, but some other patients—who have reported him to the FDA. I think he lives in a fantasy world. He's just waiting for things to die down. He might pick up and move someplace else. He got some of his machines out of his offices before the FDA was able to go in and confiscate all of them, and he could turn up anywhere.

Mr. GILCHREST. Mr. Everitt, under Idaho law, if Mr. Rapsemanakis was in Idaho right now, or if he did what he did in Nevada or Utah, wherever it was, if he did that in Idaho, could he be arrested?

Mr. EVERITT. Yes; he could. We would have had to make a lengthy case under the grand theft statute 2 years ago. But now we can arrest him for practicing medicine without a license.

Mr. GILCHREST. He is now in Nevada.

So, what is the agreement between Idaho and Nevada in cases like this?

Mr. EVERITT. We don't have an agreement between Idaho and Nevada. If it happens, it happens on an investigative level. I call the Reno police department or the Las Vegas police department, and we will cooperate, but there is no formal agreement. We can extradite from one to the other if we found he was practicing in Idaho and living in Nevada, but other than that, unless it comes under a Federal umbrella, it's very difficult sometimes to coordinate those kinds of cases.

Mr. GILCHREST. That's a good point.

If Mrs. Spencer contacted you at the time that all of this was going on, what could you have done?

Mr. EVERITT. We could have provided information to the Nevada authorities. Basically, from that aspect, if Nevada had asked us to come in and join them, we would have done so. But that probably was not the case, I believe, under her situation, and we do not have investigative authority in Nevada at the State level.

Mr. GILCHREST. So, this clinic that Mr. Read went to in Nevada, the laws in Nevada regarding that type of fraud and quackery are nowhere near as stringent as the laws in Idaho are right now?

Mr. **Everitt**. I cannot speak for Nevada, sir. I am not familiar with their laws. All I know is in Idaho, if you did those kinds of things in our State, you would be arrested for practicing medicine without a license—at the very least.

Mr. **Gilchrest**. Have these machines, the first one you showed us, ever had any prior use? Did someone take an existing machine and convert it to this type of medicine?

Mr. **Everitt**. At one time, the theory is it could have been made into a radio.

[Laughter.]

Part of this device here is also claimed that—this is in the literature that these gentlemen send out—if you want to cure boll weevil infestation of your crop, you can put a photograph of your field out there and the insecticide, and you can even put a boll weevil in the well and broadcast this curative crop thing to your field. I thought these would go very well down South.

Mr. **Gilchrest**. Are you going to testify before the Department of Agriculture?

Mr. **Everitt**. I could if you like, sir.

[Laughter.]

Mr. **Gilchrest**. The Ag Committee right after this.

Mr. **Everitt**. That is one of the uses that was explained in the brochures that these manufacturers send out. They use that as an example.

What they really say is, "Experiment with this on your crop, but what we really want you to look at is cancer, leukemia, and AIDS." We have records that we seized that state the names of patients obviously who are 94 percent cured, 79 percent cured, hundreds of names, where they will predict the percentage of cure by using these devices.

Mr. **Gilchrest**. What does Dr. Solomon do right now for a living?

Mr. **Everitt**. I can't really tell you that right now. I'm sure he's not very happy this morning, and I don't have a clue of what he's up to right now.

He is tied to our office at this particular stage. He is on probation. We do have access to him.

Mr. **Gilchrest**. Mr. Read, the doctors that you visited in the clinic, do you feel they know exactly what they're doing, that they know they're wrong in their diagnosis, and they're in it for the money, or do you think, for whatever reasoning power they might have, that they believe what they're doing is the right thing?

Mr. **Read**. Personally, I believe that they believe what they're doing is the right thing, although certainly it's lucrative. From their conversations with us, they appear to believe in what they're doing, and believe that they do not need scientific studies to prove what they're doing, and the testimonials of their patients speak for themselves. That may just be a front. I can't impugn their motives, but that's the appearance.

Certainly, the testimonies of the patients are very strong, which I'm sure is the case with Mrs. Spencer's mother. Testimonies are strong, and people don't realize to get a second or sometimes a third opinion, to look deeper into what may on the surface appear to be quite compelling.

Mr. GILCHREST. I want to thank all of you for your courageous testimony and very important information. We certainly will pursue this as aggressively as possible to prevent this from harming other people in the future.

Thank you, Mr. Chairman.

Chairman WYDEN. I thank the gentleman for his helpful questions.

The gentleman from Idaho?

Mr. STALLINGS. Thank you, Mr. Chairman. Mr. Everitt, when you confiscated this equipment, you also probably confiscated the records of Dr. Solomon.

Mr. EVERITT. Yes, sir.

Mr. STALLINGS. Could you give the committee some idea of how many of these units he would sell in a year, or how many units he has record of selling?

Mr. EVERITT. I am glad you asked me that. We believe that he has sold through the Bouchet Enterprises, which is the actual manufacturer and copartner of Mr. Solomon, thousands of these devices. Mr. Bouchet, who ran a manufacturing kind of a shop in Buhl, was getting royalties from sales of the devices from the other distributors throughout the United States. We know that they have sold thousands of them.

We have lists right here for a 90-day period of the kinds of devices and the prices that they were sold. We have every document that both the distributor and the manufacturer had of everything, and we are waiting to go.

Mr. STALLINGS. So, you would say thousands?

Mr. EVERITT. Exactly.

Mr. STALLINGS. They are selling nationwide for $1,000, $1,500, or $1,600 a machine?

Mr. EVERITT. Some range from as low as $95 to $100 for the kind that you would carry in your car or on your belt to the kind that you would take home with you, such as the big wooden one there. It is about $1,600.

There is a wide breakdown. The distributors get about a $350 kickback for selling these things in the other States. So, the manufacturer, obviously, gets much more money.

There is only about $50 worth of electronic device material inside each one of these boxes, so there is quite a markup.

Mr. STALLINGS. You say most of these devices are patented? That they have gone before the Patent Office?

Mr. EVERITT. Yes; from what I understand, they are patented, and we know that the manufacturer is receiving royalties through the mail.

Mr. STALLINGS. Incredible.

Mr. Read, was the attorney general in Nevada interested at all in your investigative report? Do you have any knowledge of any ongoing investigation by the authorities of that State of this clinic?

Mr. READ. Before we produced a report, or in our research, we looked to see if there were any kind of investigations. The problem is in many cases when investigations are in progress, for understandable reasons, they are not allowed to tell us. But we found no indication of one.

The Attorney General's Office does have an attorney who represents the Homeopathic Board. In many cases, when we looked around, we were directed to the Homeopathic Board of Medical Examiners in that State, which, at the time, said there was an investigation; there was a complaint that they were investigating, but that is all they could tell us unless they took action. So, this board investigates its own members. Dr. Tang, from what I believe, was a prior member of that board.

The only investigation we did find, and we are glad to see it, was an investigation by the FDA. As we mention in the report, they had executed at least two search warrants and seized all the dermatrons that they could find while they were there, along with numerous other medications and documentation. I believe that was in 1990, so it has been quite some time since that investigation started, and I don't know. Perhaps the gentleman from the FDA can tell us where that stands today.

Mr. STALLINGS. Mr. Everitt, watching this video tape, would there be a cause of action in Idaho?

Mr. EVERITT. There has been.

Mr. STALLINGS. I mean, if they had that kind of practice, that kind of investigative report on a doctor in Boise or a clinic in Boise, could your office take action?

Mr. EVERITT. Yes, sir; we have. That same device that he was being treated on, I have gone under cover on in Boise. I was treated for Epstein-Barr disease, which I didn't have.

Mr. STALLINGS. Can you tell the committee what Epstein-Barr is?

Mr. EVERITT. I am not sure that I know.

[Laughter.]

Mr. EVERITT. I went into a reported doctor in Boise. We knew that he had an Intero, a more sophisticated computer device similar—I think, actually, ours is a little more high technology than the one that you saw.

I complained of having Epstein-Barr, being tired and rundown all the time, and he asked me to bring in a jug of water from my well, which I promptly went to the forensic laboratory there in Boise and got a sample of the purest water that they would dream up. I found out that the water that I was drinking was the cause of my problem, and I was put on a regimen of tinctures and so forth. Didn't take any of them, obviously. But I was pronounced relatively cured in about 4 weeks.

We seized the device. That individual was provided to the FDA to provide testimony against other manufacturers of the devices.

Yes; we go after these guys.

Mr. STALLINGS. Now, you would not be able to get them for practicing without a license, because, obviously, Mr. Read said that the one fellow was a Harvard-trained doctor. Would there be other statutes?

Mr. EVERITT. Yes, sir; grand theft by false promise is one that we have used. Obviously, the device was deemed by the FDA as being ineffective and unsafe, and we would use that statute. It would be better for Federal prosecution under those kinds of situations. It is very difficult to educate local prosecutors about these kinds of cases.

Mr. **Stallings.** Sheri, let me ask a couple of questions to you. You did an excellent job. We appreciate your heartfelt testimony here. It certainly gives us all pause to consider. Our own family could go through something like that. When one becomes afflicted with these diseases, sometimes reason is not the most important thing in our life.

Why did your mother fear traditional medicine? Or did she? The impression I got here was that there was some concern that the regular doctors made her nervous, or maybe she wasn't very comfortable in that situation?

Mrs. **Spencer.** My mother's mother had been diagnosed with breast cancer, and she had had a radical mastectomy, and I know that was very hard on the family. It was long before they did implants or anything. My mother's brother in the sixties had contracted Hodgkin's disease, and he had gotten extensive radiation treatment at that time, and he had subsequently passed away also. I think she looked at the medical profession not as a problem solver because to her the problems were still there.

Dr. Rapsemanakis was not the first alternative medical professional that she went to. There is a long line of them she had seen previous to that.

Mr. **Stallings.** Do you have any way of knowing how much she spent on this gentleman from Nevada?

Mrs. **Spencer.** I can only guess. But I am sure it was extensive. I am sure it was above $10,000.

Mr. **Stallings.** When you called the Nevada Medical Society, did they ever give you any indication that they were worried about this particular clinic?

Mrs. **Spencer.** I was never able to reach the Nevada Medical Society. All I talked to was an operator who gave me some phone numbers that I could call, one of which was disconnected, and the other one gave me the Humana Hospital and they said, "Gee! We don't know who you should talk to."

Mr. **Stallings.** How quickly did the FDA respond to your request?

Mrs. **Spencer.** I talked to Dr. Jarvis in August and the FDA contacted me the same day Grady did. That would be March 17th.

Mr. **Stallings.** When your mother passed away, was she still convinced that the treatments had helped?

Mrs. **Spencer.** When my mother passed away, she wasn't able to communicate at all, so I am not sure. But the last efforts that she made were still very kind and positive toward Dr. Rapsemanakis, so I think she was.

Mr. **Stallings.** You said that some of your family is still convinced that the treatments had helped?

Mrs. **Spencer.** Yes.

Mr. **Stallings.** Ladies and gentlemen, Mr. Chairman, that concludes my questions. I appreciate this opportunity. I think this has been very helpful, and I think the panel has given us good information.

I would certainly join with you, Mr. Chairman, in working for the legislative resolution of this problem.

Chairman WYDEN. Well, I want to thank my colleague. Having been to Boise with him to address health care and aging issues, I know of his longstanding commitments to these issues.

We are going to be pursuing these issues both on the legislative and the administrative fronts.

We have got a vote on. Let me see if I can ask a question or two, and then with this panel's indulgence, I would like to see if you all can stay for a few minutes. I am just going to run over and vote and come back.

My first question, Mr. Everitt, if I might, is do you think that the Food and Drug Administration telegraphs too much to the quack device manufacturers when they initially open a case? I sense from your comments that initial warning letters, based on what you see on the front lines, often gives some of these quacks and charlatans a chance to get an early warning and slip away.

Mr. EVERITT. From my perspective, it seems that is the case. A lot of the regulatory requirements that they are required to do at the local level or through the field offices seem to give these guys an awful lot of advance warning that they are attracting the interest of an investigator or an investigative entity.

It would seem much better from an investigative point of view that I will develop my case, get the evidence that I need, and then I will come in and take it before it has a chance to be altered or taken someplace else.

Chairman WYDEN. That is our second bell, which means we have really got to zip. I am going to have some more questions. I want to follow up with you, Mr. Everitt on the Federal Government's role, and particularly the Federal Government in its connection with the States. I have some questions for you, Mr. Read, and you, Mrs. Spencer, as well.

With your indulgence, the subcommittee will stand in recess for about 10 minutes.

[Recess.]

Chairman WYDEN. The subcommittee will come back to order. I appreciate the indulgence of our witnesses as it is going to be a hectic day, but we are anxious to get your additional feedback.

Now, Mr. Everitt, I appreciate what you have just given us, particularly with respect to this matter of the FDA telegraphing its interest in a case in a number of instances to these quack device manufacturers. I think that this is a big problem, and we are certainly going to follow it up.

I also share your view that the regional offices—we deal with the Seattle office—try very hard to deal with these matters as well. However, what is your sense of what happens when it goes to the national office of the FDA.

Mr. EVERITT. That is very difficult for me to explain because I am not in the internal workings of the FDA. It has been explained to me that there are various ad hoc committees that review this kind of information, prioritize an investigation based on the current strengths and investigative endeavors, and then it goes to, I guess, other committees, and if they decide that they can prosecute it, then they get back to the original office and give instructions.

Chairman WYDEN. But I think what you have said is in line with what we have heard elsewhere. Somehow, this information just bounces around the Federal labyrinth and goes nowhere. It seems to me that what you and other enforcement officers are calling for is something along the lines of a Federal fraud information clearinghouse, a place where this information would go, and then be disseminated quickly to various States and local governmental bodies. I also think we need something resembling a national fraud strategy rather than a case-by-case effort that sends each local and State official off on their own.

Mr. **Everitt**. We found that the critical days of an investigation like this are from the first 5, 10, or 15 days. Information gets out quite quickly that a tentacle has been worked on by an authority. We need to be able to submit to the FDA a case that we have through their regional office and have a quick return on the decision as to whether to incorporate the State findings. In this case, this is a silver platter case where we have all of the documents for an entire operation throughout the United States. That kind of information should go quickly to the FDA.

Chairman **Wyden**. I think that is a very compelling point. I think that what has happened is that as crooks have taken advantage of the state-of-the-art technologies and new marketing approaches, the Federal Government has been a step or two behind. There are many good people out in Federal regional enforcement offices, and there are good people operating in State and local law enforcement, but unless we have a coordinated national effort, I think the bad guys are going to slip between the cracks. They are simply going to move on to another jurisdiction, from State to State and community to community, and continue to inflict the kind of carnage that you and others describe. I think you make a very compelling case.

Now, there is just one other area that I wanted to ask you about, Mr. Everitt. It has been the subcommittee's finding that in the vast majority of these health care frauds little or nothing is said by the practitioner or inventor about these devices in writing. The perpetrators say as much as they possibly can verbally, and verbally they engage in very aggressive, hard sell techniques, but very little is actually claimed down on paper.

Does that square with what you have found?

Mr. **Everitt**. Exactly.

Chairman **Wyden**. OK. Let me move on to you, Mr. Read. Is it your sense that the term doctor is being thrown around pretty indiscriminately in the area of these health care frauds? What we have begun to sense is that a doctor may mean a doctor in a wide variety of fields from engineering to something that resembles traditional medical practice, and that more and more instances of these kinds of frauds involve people who may have a medical license somewhere, the United States or elsewhere, but are clearly out of their area of expertise and are simply hiding behind the title of doctor. Are you finding that that is the case?

Mr. **Read**. Well, certainly in this case, Dr. Tang is a Harvard Medical School graduate, and that is impressive credentials for anyone visiting the clinic. So, he is properly credentialed, and I assume able to prescribe the kind of treatment he sees fit. As far as his wife, even though she has a medical, or appears to have according to the records, a medical degree from another country, it would be my personal opinion that I think she should be qualified to practice in the United States before obtaining a homeopathic or any other kind of specialty license. I don't believe that is the case, or it certainly wasn't when she was licensed in Nevada. Additionally, and perhaps even worse, is that Dr. Yiwen Tang's license to practice medicine in the State of California had been suspended for 5 years while he was building his practice in Nevada.

Chairman **Wyden**. But citizens who go to see these doctors that you have investigated believe that they are seeing a doctor, and that the doctor first, has a degree, second, has a license, and third, has expertise in a particular specialty. I gather that in many instances that is not true, but the doctors just hide behind their title to be safe from significant enforcement efforts?

Mr. **Read**. I would say so. I would also say that a degree, or a degree that was gained in 1947, may look impressive, and it is hard for the public to determine, but they have to look behind the initial credentials and have to try and look at what people are doing today.

Chairman **Wyden**. This is an area that the subcommittee is going to be looking at much more in the future. Because my sense is you can pick up the Yellow Pages in any community around this country and you can see physicians who, in effect, misrepresent their credentials right there in the Yellow Pages. They hold themselves out as specialists in a particular area when, in fact, they just have a degree and a license. It is wrong to have people relying on a claim of expertise that they don't have.

Now, if I might, Mrs. Spencer, I am not clear in your instance whether your parents felt that they were visiting a traditional medical doctor—a physician doctor who graduated from medical school—or whether they knew that this individual had another sort of degree.

What was the understanding of your parents in that case?

Mrs. **Spencer**. My mother told me that this man did not have a medical degree, but that he had done countless hours of research in that field. He said that his degree was as a scientist, as an engineer of some sort, and that he had a Ph.D. in that field.

When the news asked him what his degree was and why they called him doctor, he mentioned that he was a "Doctor of Divinity."

Chairman **Wyden**. But your sense is that your mother thought that there was at least enough training and expertise in the particular medical specialty and that this person could be called doctor, and that he held out to her a promise of real hope in this particular area?

Mrs. **Spencer**. Yes; that is correct.

Chairman **Wyden**. I think the only other question that I had for this panel dealt again with the Federal Government, and maybe, Mr. Everitt, that is best posed to you. The States seem to be trying hard to share more information, and particularly to get this information out in a more timely fashion. In terms of a clearinghouse approach, a national coordinated strategy, is this an area where you would like to see the Federal Government move aggressively to make information available so that the States, in effect, don't always have to send information to the Feds and never get anything in return?

Mr. EVERITT. Early on in this particular case, we talked about wouldn't it be nice if we could all get together under one task force operation and work. Just the remnants of this particular case could keep us busy for the next 3 years, and working all the spinoffs that come from an investigation such as this or any other investigation along that line.

We think that this investigative umbrella that the FDA could provide would be very, very helpful to all of the State agencies across the board.

Chairman WYDEN. Well, you all have been an excellent panel. We are going to be relying on you in the future. It has been very helpful testimony. We will excuse you at this time. Thank you.

Our next panel: Dr. John Renner, M.D., Consumer Health Information, Kansas City, Missouri; Mr. Robert Reyna, assistant attorney general, Office of the Attorney General, Dallas, Texas; and Mr. Ronald M. Johnson, Director, Office of Compliance, Center for Devices and Radiological Health, FDA, Rockville, Maryland.

Chairman WYDEN. All right. We have more bodies at the table than I have in front of me, and I want to make sure that I have got everyone properly identified. Dr. Renner, Mr. Reyna, Mr. Johnson, and Mr. Johnson, you are accompanied by several associates.

Mr. JOHNSON. Yes; I am.

Chairman WYDEN. OK. Why don't you identify them for the record?

Mr. JOHNSON. This is Gerald Vince, who is the Director of our Office of Regional Operations of the FDA, assigned to the Office of Regulatory Affairs.

This is Mr. Heinz Wilms, who is the Director of the Division of Federal/State Relations.

Chairman WYDEN. Good. Now, Mr. Johnson, do you anticipate that your associates may be responding to some of the questions as well?

Mr. JOHNSON. Yes, sir.

Chairman WYDEN. OK. Why don't we swear all of you in at this time?

Let me first ask, do any of you have an objection to being sworn as a witness?

Chairman WYDEN. OK. Please rise and raise your right hand.

[Witnesses sworn.]

Chairman WYDEN. Gentlemen, I am going to have to ask each of you to keep your prepared remarks to about 5 minutes, because this is going to be a very hectic morning. We are going to enter your prepared remarks into the hearing record in their entirety, so all of your prepared remarks will be a part of the hearing record fully, and I very much appreciate your indulgence. The fact is that this is a day with much to make it difficult for Members to focus, and we appreciate it.

Dr. Renner.

TESTIMONY OF JOHN H. RENNER, FAMILY PHYSICIAN, AND PRESIDENT, CONSUMER HEALTH INFORMATION, RESEARCH INSTITUTE [CHIRI]

Dr. RENNER. Congressman Wyden and other members of the committee, I appreciate this opportunity. I am a family physician. I am deeply involved in consumer health education activities and have been studying quackery as a part of my daily work for the last 10 years. I go to quack conventions. I talk to quacks almost every day on the phone. I talk to victims of quackery every day on the phone. I hear complaints from legitimate physicians. I talk to a variety of Government agencies on a regular basis. I have been the cosponsor of the National Health Fraud Conference with Food and Drug Administration. I have an extensive file on quackery. I subscribe to all kinds of newsletters and publications that organized quackery groups put out. I have also filed suit in Federal court against some quacks, and have, through the discovery process, received a lot of information that I otherwise would not have been able to get a hold of had I not filed that lawsuit. I also get copies of lawsuits from different court jurisdictions around the United States. I give lots of talks on quackery, and especially I am trying to inform the medical profession on what quackery is all about because almost no medical school in this country has any organized classes that teach physicians about what they are going to run into in the form of quackery. Most physicians are absolutely mystified when they eventually learn what their patients are running into.

I have been studying various disciplines that get involved in quackery, and I would like to, for the first time, present to you publicly the fact that of the 630,000 M.D.'s in the United States, I estimate 1 percent of them are involved in quackery. I am not talking about economic fraud. I am talking about quackery. I make a distinct differentiation there.

If those estimates are true, that is 6,300 M.D.'s who could easily be grossing $200,000 a year—that is a very conservative estimate—to over $1 billion. I estimate that 10 percent of osteopathic physicians are involved in it, and I have submitted for the record estimates of what this total is going to come up with. But I would like to make sure the committee understands that quackery is not just practiced by M.D.'s and D.O.'s, but also chiropractors, nurses, and pharmacists, and yes, even a few veterinarians. Because we have veterinarians who are taking care of humans, and I have marketing tapes where when people bring their pets in for treatment veterinarians will clip fingernails and hair, and start to do analysis on humans, and, thereby, get involved in human health care as well.

We have dentists who are involved in quackery. The different percentages for different professions, I have tried to be as careful as I can. I have a large number of quackery directories because these people self-advertise, and my estimates are based on data that I have gleaned from those directories.

There are all kinds of gimmicks and gadgets that are used. But I also want to emphasize that anybody who wants to be a quack can use an ordinary microscope, an ordinary urine analysis machine, and misinterpret it, or they can send laboratory samples out to a widely respected laboratory. If they want to practice quackery, all they have to do is to take the normals that are on that lab report and narrow them down and now start to say that their range of normals is much narrower than what the lab report was, even from a company that is authentic and does legitimate lab work. So, it doesn't take a device to be a quack.

It helps, especially if it is a mysterious device that does things that ordinary medicine can't. I brought one such gadget that was brought to me by a family in Iowa. This gadget was able to analyze a Polaroid film and the energy level that comes out of a Polaroid film, no matter whether it was a picture of your body, a picture of your fields, your crops, whatever. It could analyze pesticides. It had multiple purposes. This gadget sold for $2,000.

This was used inappropriately to diagnose allergy in a young woman, and it has totally destroyed her life, because she now is convinced that she is allergic to everything.

Dieticians in this country seem to be immunized against quackery. Only a very small number of trained dietitians become involved in quackery. I estimate less than two-tenths of 1 percent. They get information about nutrition quackery health fraud in their own educational program. I think educating the public is useful, but I think also making sure that the professions are educated is equally important.

We also have a large number of laypeople in this country who have set up multilevel sales organizations that are grossing hundreds of millions of dollars, that have hundreds of thousands of salespeople, and I know that tab is going to exceed $20 billion a year alone. So, I have submitted a total of what I would consider to be an extremely conservative estimate of the cost of quackery at in excess of $31 billion.

Quackery is highly organized in this country. Every State has quack organizations. I am doing a ranking, State by State, of which States are the quackiest. I have 20 some criteria in that indices, and I will be glad to provide that to you when that study is done. But I will tell you that Oregon is going to be in the top 20. North Carolina may make it, but I am not quite sure. If they do it will be in the teens. But Colorado is definitely in the top 10, so is California, Oregon, and Texas. I hope those criteria are going to be fair to all States concerned.

For a while I didn't think Vermont had any quacks, but we have recently discovered several. Once you find a few you are led to others. So, every State, for that matter every country in the world, has quackery in it. I have recently been studying some quackery that is being exported from the United States to Australia and New Zealand. So, I can assure you it is not just a phenomenon here.

You have asked some very, very good questions here today. I think one thing that needs to be made very, very clear is that devices are just one way that quackery is promoted. Because practitioners are the ones who carry out quackery, whether they are licensed or unlicensed, in some States the State licensing laws are so bizarre that practicing medicine without a license is a misdemeanor and may be fined by a $500 fine. Somehow, we have got to find a way that the penalty for practicing medicine without a license is much more than a misdemeanor.

I think we also need some kind of laws that protect people who turn people in to the FDA. A lot of FDA's problems are because people are aware of things for 6 months to 1 or 2 years, but they are afraid to turn something in because they are afraid their name is going to be made public, and they are going to end up being a witness or somehow sued, as we heard this quack in Nevada turned and even sued his own patients for turning him in to a newspaper reporter.

If we could have some kind of Federal good samaritan laws that protect consumers and consumer groups from that kind of legal retribution, I think it could be very, very helpful.

I think also we need to do a better job of educating the media. In many cases, the media, particularly television talk shows, have made some quacks appear to be folk heroes. I can tell you after one quack was on one talk show in this country his office received 15,000 telephone calls. It was not an expose of that quack. It was a marketing of that particular quack's activity. I think that the media especially needs to know what happens if they make some of these individuals appear to be folk heroes.

The elderly, in particular, are marketed, and I will just give you one specific example. A few months back, there was a lot of publicity on mercury amalgam fillings. We have dentists and physicians in this country who are trying to convince people that they ought to have their amalgam fillings removed. Here is a book that has just been recently written that recommends mercury testing for elderly people because they can get rid of Alzheimer's disease, and they put people on all kinds of remedies, but ultimately recommend that they have their mercury amalgam fillings taken out.

Now, in some States if a dentist does that they could lose their license. But in other States that is not an illegal act. I just mention that as one way that a gadget is marketed within a specific illness.

Here is a gadget that all of us are paying because our health insurance pays for this gadget in many jurisdictions. It is called an activator. It is a spring-loaded thumper that thumps your spine or your TMJ or anything that "is out of place." It thumps you with 27 pounds of pressure. But it is a widely accepted gadget in the field of chiropractic. I know of no scientific evidence that shows that this works, but we are all paying for it through a variety of health insurance.

I think, also, Congress needs to look at some of the laws that they have passed over the years that, in essence, make it easier for quacks to operate. Homeopathy is legal in this country. I think if we look at the science of homeopathy, the theory that something that is more dilute is stronger than something less dilute, we really need to ask do we need those kinds of legalization of scientific nonsense on the books. It may be time to look at some of those laws.

I think also you are going to be faced with some very difficult decisions in food labeling and food supplement labeling that is coming up, and that would be a good place to put your foot down if you really want to fight quackery.

All kinds of mysterious things are marketed. The last time this committee had hearings, there were electronic mattresses, or magnetic mattresses that were a part of it. Well, the magnets haven't gone away, but here is the new version of them. These are magnetized footpads that will help you set up proper electrical waves up and down your body. These are being sold very aggressively along with $1,500 mattresses that you are supposed to sleep on to get your electronic circulation in order.

Chairman WYDEN. Dr. Renner, I am sorry, but we are just going to have to wrap it up.

Dr. RENNER. All right. I will conclude my remarks then.

[Dr. Renner's statement, with attachment, may be found in the appendix.]

Chairman WYDEN. We will have some questions for you in a moment.

Chairman WYDEN. Mr. Reyna.

TESTIMONY OF ROBERT E. REYNA, ASSISTANT ATTORNEY GENERAL, CONSUMER PROTECTION DIVISION, OFFICE OF THE ATTORNEY GENERAL OF TEXAS

Mr. REYNA. Mr. Chairman, I am going to shorten my prepared comments and limit myself to two of the areas that I was asked to address by the committee. I am going to talk about the steps we are currently taking to improve Federal/State coordination in the area of device investigation, and I am also going to give you my comments regarding possible claims of preemption that are being raised in the area of medical devices that are preventing private causes of action and could prevent some investigations of ours from proceeding under a mistaken idea that the Food and Drug Act preempts State enforcement in the area of devices. Some Federal judges have been accepting that argument recently.

Through cooperative efforts of the National Association of Attorneys General and the Food and Drug Administration at the urging of Dr. Kessler, when he became FDA Commissioner, we formed a working group of assistant attorneys general that monitor on a regular basis any reports of potential health fraud being perpetrated through devices as well as through food and drugs. We feel that our initiative in the area of devices is especially important because the prosecution of device frauds, which are largely economic crimes against consumers, is our business in State consumer protection units.

By the nature of its mission, the FDA is required to prioritize a number of its investigative efforts. Food and drugs, by definition, have had a higher investigative profile than the device area has. Mere economic crimes, as opposed to immediate risk to health, have had the lowest priority even in device investigations.

I believe that a period of time existed in which there were limitations in the resources that could be brought to bear on these investigations. I don't believe that exists now, and does not need to exist. The States have sufficient investigative resources that they can allocate to prosecute violations of the Food and Drug Act and the State acts. In Texas, that has proven to be a significantly easier process because our State has passed a model Food and Drug Act which mirrors the Federal act. We are able to move rapidly against these frauds. In fact, I think you will hear that the FDA has come to rely on us to do that.

A matter of extreme concern to us is that the elderly are particularly susceptible to these types of fraud, whether it is the marketing of these diagnostics, pain relief devices, tapes which tell you they can lower your cholesterol or change the shape of your body, or magnets that you put in your mattress. I have touched, in the first part of our talk paper, on some of these devices and some other types of cases that we have brought, and those are covered in my material.

Whatever authority the attorneys general can be given that they could give priority to these types of cases, we would certainly welcome expanded authority to bring cases either directly in Federal court or to use our State act to directly enforce the Food and Drug Act in State court.

Our agencies are ones which, in a good number of States, place a high priority on bringing public interest cases, especially in the area of health and safety, whether it is just a consumer fraud or whether it is an actual violation of the Food and Drug Act.

We have had a number of significant successes, and we feel that we will be bringing even more on a regular basis as the FDA comes to look at the States through the working group to get rapid enforcement.

Finally, I would like to address attention to the matter of preemption in the device area. I apologize for this being a little bit technical. We do want to get our position on the record.

The current preemption provision is overly vague and has resulted in some court decisions finding preemption where there should be none. We believe that there is no need for preemption in this area. On the State enforcement level, we generally coordinate our efforts with the FDA to ensure a consistent State/Federal approach to a particular problem.

Moreover, in those areas where there is an actual conflict between the State and the Federal scheme, existing constitutional principles of conflict preemption ensure that a manufacturer is not put in a Catch-22 situation of having to violate Federal law to comply with the State law.

If preemption in this area is to continue, we believe Congress should act to clarify just which State laws are preempted. We have two primary concerns.

First, there should be no preemption of State law unless the FDA has taken a definitive action with respect to a device. This means that the FDA has thoroughly considered an issue and promulgated a requirement that is both a ceiling and a floor as is the case with performance standards for class II devices presently.

There should be no preemption where the FDA has merely imposed minimum requirements. For example, recent court decisions have found preemption because the FDA has granted premarket approval to a particular medical device. Premarket approval is just a floor. It does not guarantee the ultimate safety of that device. The current breast implant controversy is a clear example of the fact that devices once considered safe can become considered unsafe as more is learned about them. In the absence of a definitive Federal guarantee of safety, there should be no preemption of State law measures that enhance the safety of a device.

Second, there should be no preemption of State tort laws and other victim compensation measures. FDA action always involves a balancing of risk versus benefit. A device that may well be dangerous to a small number of people may be approved if the benefits outweigh the risks. Recent court decisions have found complete preemption of tort remedies in the device area. This is particularly unfair in light of the fact that at the time of approval is expected that some devices will, in fact, have harmful side effects. If a device injures a person and the manufacturer of the device has violated a State law that would compensate a person for that injury, then an FDA determination that the device may be sold, even though it has some harmful side effects, should not bar that person from just compensation.

Thank you.

Chairman WYDEN. Thank you very much. Your full statement is going to be made a part of the record.

[Mr. Reyna's statement may be found in the appendix.]

Chairman WYDEN. Thank you very much. Your full statement is going to be made a part of the record.

Mr. Johnson.

TESTIMONY OF RONALD M. JOHNSON, DIRECTOR, OFFICE OF COMPLIANCE AND SURVEILLANCE, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY GERALD VINCE, DIRECTOR, OFFICE OF REGIONAL OPERATIONS, AND HEINZ WILMS, DIRECTOR, DIVISION OF FEDERAL-STATE RELATIONS

Mr. JOHNSON. For purposes of time, I won't read from my prepared statement, but I would like to make a couple of general comments.

I think, Mr. Chairman, you're aware of the Food and Drug Administration's efforts under Dr. Kessler's tutelage to move enforcement up a notch to make it more visible. Clearly, in the Center for Devices, we are in tune with that, and I think Mr. Benson, in his testimony before Mr. Dingell, expressed our desires in that regard.

In that light, in looking at our activities in health fraud, we have exercised a number of traditional regulatory tools, but I think in looking at what we have done recently, the trend there is similar to the trend we find elsewhere in the device area; that is, we are taking more actions.

In the first half of fiscal year 1992, we have processed 16 seizures. That may not sound like a lot, but compared to the 6 that were processed in all of 1991, and the 3 the year before, I think it's a significant increase.

But more importantly, I think, we are looking at health fraud in a much different light than we have historically. We recognize that the nature of the health fraud industry is here today, gone tomorrow, and that we are dealing for the most part with the cockroaches of the world, if you will, and we have to adjust our tactics accordingly.

One of the tactics that we have embraced is the utilization of the skills that we've developed over the last 2 years as a result of our experience with the steroid investigations. Principally, we have honed and developed criminal investigative skills that heretofore we have not had. We are bringing those skills to bear in the health fraud industry. While we have—and I wish that I could give you more information—we have a number of large-scale, nationwide investigations ongoing, working with the Department of Justice and grand juries throughout the country, I can't give you more details than that. But I think that if you look at simply the numbers of searches and seizures, you can see increased activity in that direction. In 1990, we had no searches and seizures, but within the last 2 years we have had six where we have seized large numbers of devices and documents, all in the pursuit of criminal actions. We have three search and seizure actions that we're currently reviewing now.

So, I think our strategy on health fraud is much different. I think it is more in tune with some of the comments that have been made to you earlier today, about the strategy that should be followed in dealing with health fraud.

We, of course, are continuing our educational campaign. We think an informed consumer clearly is a major component in attacking and dealing with health fraud.

We have, for a long time, and continue to have, a very good working relationship with the various States, as well as Federal cooperating agencies.

I will take any questions.

[Mr. Johnson's statement may be found in the appendix.]

Chairman WYDEN. The gentleman from North Carolina.

Mr. LANCASTER. Mr. Johnson, what is the total number of employees at FDA devoted to investigation of this type of devices and other health care fraud?

Mr. JOHNSON. Let me answer in general. We have a staff of field investigators that investigate virtually all of the commodities that we regulate. Mr. Vince can give you a number for that.

Mr. VINCE. Almost 1,100, sir.

Mr. JOHNSON. Eleven hundred.

Mr. LANCASTER. How many of those are focused on health care fraud of this type, quackery?

Mr. JOHNSON. Well, I think we can tell you what we have spent in the number of hours that we've expended specific to health fraud, with an understanding that many of the activities we do aren't actually credited specifically to health fraud.

In 1986 to 1991, we increased the numbers of investigational hours that were actually spent by a factor of 10, so I think we have significantly——

Mr. LANCASTER. All right. Did you go from 1 to 10 or did you go from——

Mr. JOHNSON. We went, in one specific program area, we went to about seven or eight FTE's, full-time equivalent person years.

Mr. LANCASTER. In the whole country?

Mr. JOHNSON. In one specific program area, in the health fraud program area.

Mr. LANCASTER. That's what I'm saying. In health care fraud, you had the equivalent of seven full-time employees nationwide?

Mr. JOHNSON. For devices.

Mr. VINCE. If I may expand on that, sir, Mr. Johnson is relating to the device area. But from the overall perspective of the field investigative activities—which includes obviously devices, drugs, biologics, foods, and the other commodities that we regulate—our expenditure in FTEE's last year was slightly over 50, and it is projected to be just about that level, if not greater, this year.

Mr. LANCASTER. That is 50 out of 1,100?

Mr. VINCE. Yes, sir.

Mr. LANCASTER. Now, what do you think is the appropriate level of investigative support for this kind of investigation? Is 50 appropriate for you to be doing all that needs to be done in this area?

Mr. VINCE. We have certainly increased our resources——

Mr. LANCASTER. That was not my question. Do you think it is the appropriate level?

Mr. VINCE. We can always use more resources to do more things.

Mr. LANCASTER. OK. How much more resources do you need in this particular area to do the job that you believe needs to be done in health care fraud?

Mr. VINCE. It's a very difficult question to answer, obviously, because we have developed a network, working with both the fellow representatives in our State and local organizations. As we learn more about it, there is obviously more crime—I believe that's the term was used earlier today—out there that we would be able to direct resources to.

Mr. LANCASTER. I'm sorry, I don't know your name.

Mr. VINCE. My name is Gerald Vince.

Mr. LANCASTER. Mr. Vince, you still haven't answered my question. I want to know specifically what you think the appropriate level of staff support in this particular area of investigation is. Is it 100 FTEE, or is it the 50 that you devoted last year, or is it 1,000?

If you can't give me a specific number, tell me, is it double what you've got now, 25 percent more than what you've got now? Give me some idea of what you think is appropriate for the problem that exists.

Mr. VINCE. The problem is extremely difficult to define, but, on the other hand, as you obviously desire a number, I believe we could probably utilize between 25 and 50 percent additional staff to more effectively address this problem.

Mr. LANCASTER. Has the FDA made a request for additional staffing in this area?

Mr. VINCE. I can't answer that myself, sir.

Mr. LANCASTER. Is there anyone here today who can?

Mr. VINCE. Not as part of our panel, sir.

Mr. LANCASTER. OK. Could you provide from the FDA, from Dr. Kessler or whoever, information to this subcommittee as to whether or not additional resources have been requested for this particular field of investigation, and, if so, what was requested and what was the disposition of that request?

Mr. VINCE. All right.

[The information was not received.]

Mr. LANCASTER. I would simply say that, in my opinion, the FDA has not devoted the resources necessary to address what I see as a real problem, not only in vulnerable and unsuspecting people wasting their hard-earned money, but in many cases the wasting of tax dollars in Medicaid and Medicare. I think, as the chairman has indicated, we should not begin to go down this road of providing universal health care for everybody until we make sure that it really is health care that we're providing with tax dollars, and not this kind of quackery that has been demonstrated here today. I believe that the FDA has a responsibility that they are not meeting, and I want to know why.

Apparently, you who have come here today are not in a position, because of the level of your policymaking, to tell us why you haven't requested or even if you have requested additional resources. Is that correct?

Mr. JOHNSON. That's correct.

Mr. VINCE. Yes, sir.

Mr. LANCASTER. Who would be the appropriate person to ask those questions of?

Mr. JOHNSON. I would imagine clearly the Commissioner's Office, the Associate Commissioner for Management, would have a clear handle on what we've requested and where we've devoted resources.

Mr. LANCASTER. Is there any particular person whose sole responsibility is to coordinate the efforts of quackery investigations, or does it just sort of happen that when somebody makes a complaint one of your field people gets involved to respond to a particular complaint?

Mr. JOHNSON. I'll try to answer that. I'm not quite sure I understand the question.

We do have specific programs that we give guidance and direction to the field forces, as to areas that need attention——

Mr. LANCASTER. I asked a very specific question. Is there a person who coordinates health care fraud investigation?

Mr. JOHNSON. For the entire agency?

Mr. LANCASTER. Yes; for the agency.

Mr. JOHNSON. I don't believe for the entire agency. For my center, there is a contact person who manages all health fraud programs, yes.

Mr. LANCASTER. What is your center?

Mr. JOHNSON. The Center for Devices.

Mr. LANCASTER. But you deal only with devices?

Mr. JOHNSON. That's correct.

Mr. LANCASTER. This is not a person who devotes full time to this effort; this just happens to be one of his collateral duties, is that correct?

Mr. JOHNSON. It's one of his principal duties, yes.

Mr. LANCASTER. So, there is nobody, as far as you know, in the FDA whose sole responsibility is to coordinate your agency's effort at ending quackery in this country?

Mr. VINCE. I would like to address that question, sir. We have a group, that has been formed in Mr. Wilms' Division of Federal-State Relations, that focuses in on the information within the agency from the various program centers—as I said earlier, those involving medical devices, drugs, biologics, foods, and veterinary medicine. Mr. Wilms is in charge of that, what we call our Health Fraud Information Staff, and in that capacity he works with representatives from each of these five centers, the programmatic centers within the organization. I believe he might be able to give you an overview of the function of that organization.

Mr. LANCASTER. That will be fine.

Mr. WILMS. I would be happy to.

As part of the operation of my Division of Federal-State Relations, we have a health fraud coordinating unit which has been placed in my division just within the last several months.

Now, it's purpose is to create a network of information sharing between the State officials—and thus, it was no accident that it comes to the Division of Federal-State Relations—and our various centers, as well as our field folks. We have health fraud coordinators located in each of our district offices, and a regional coordinator, along with key people in each one of our centers, like for foods, drugs, and devices, as well as a working group of representatives of the State attorneys general offices and Food and Drug officials in nine States around the country.

We have regular conference calls on the subject of health fraud coordination specifically, and to share with each other information that will ultimately lead to regulatory actions or educational approaches, whatever seems to be appropriate, for that particular health fraud.

Our office performs that coordinating function. I don't have that as a full-time responsibility, but it is under my direction. I have one consumer safety officer and one technician assigned to my staff for that purpose. We are currently hiring permanent staff for those two activities.

Mr. LANCASTER. Was this initiative as a result of States feeling the frustration of not getting the cooperation that they needed from your agency?

Mr. WILMS. No; I think that it came as a result of a recognition by both our leadership and the States' leadership that this is a problem that is bigger than the both of us; that it is a need for us to be sharing our resources and our respective authorities, because in some cases States have authorities we don't have and vice versa, and depending on the circumstance, it may be better to take a State action versus a Federal action.

Mr. LANCASTER. When was the initiative begun?

Mr. WILMS. This initiative regarding the transferring to my division took place in late December, January of this year, and we started operating in that mode basically in January of this year. The idea for it began after we met with the association of both Food and Drug officials and the National Association of Attorneys General in October.

Mr. LANCASTER. Do any of the three of you have suggestions for this subcommittee on changes in Federal law that you think would be helpful in investigating and prosecuting health care fraud?

Mr. JOHNSON. From the standpoint of devices, no; I don't think so. We have in the new Safe Medical Devices Act some new authorities that we are implementing now, and at this point I don't think we see any additional ones that are necessary.

Mr. LANCASTER. The three of you can speak only to devices, to no other area of health care fraud. Is that correct?

Mr. VINCE. Mr. Johnson is specifically assigned to the area that handles devices, and Mr. Wilms' and my function is a more broader perspective, but it is not in that specific nature that Mr. Johnson holds his responsibilities.

Mr. LANCASTER. OK. If we have a good statute with regard to devices, would either of you care to comment on whether there is needed legislation like that that we have on the books with devices to deal with other areas of health care fraud?

Mr. VINCE. The agency would always be certainly willing to consider any additional enforcement tools.

Mr. LANCASTER. That wasn't my question.

Mr. VINCE. We have no specific recommendations.

Mr. LANCASTER. You think the law is adequate for addressing health care fraud outside the area devices as well as within that area?

Mr. VINCE. Reasonably so.

Mr. LANCASTER. What laws are available for the use and prosecution at the Federal level of health care fraud other than in the area of devices?

Mr. VINCE. The basic statute, the Food, Drug, and Cosmetic Act, that is the cornerstone of our legislation and our enforcement authority.

Mr. LANCASTER. Can you cite me any specific provision in your basic authority which deals with this particular subject?

Mr. VINCE. Those sections that apply to civil proceedings, including seizure, interim actions against violators.

Mr. LANCASTER. I'm not talking about procedural, I'm talking about substantive law, prohibitions against any particular action that could be interpreted as health care fraud.

Mr. VINCE. There are a number of subsections under prohibited acts that would be applicable depending on the nature of the fraudulent property.

Mr. LANCASTER. Can you give me one?

Mr. VINCE. The 301(k) section would be the misbranding of a fraudulent device after its receipt in interstate commerce, whereby it has been held up to offer curative powers that it certainly was not able to provide.

Chairman WYDEN. Would the gentleman yield?

Mr. LANCASTER. Yes.

Chairman WYDEN. Are these devices misbranded?

Mr. JOHNSON. Yes.

Mr. VINCE. I would certainly think so.

Mr. LANCASTER. Have you taken any action against any of these devices at the Federal level?

Mr. JOHNSON. Yes.

Mr. LANCASTER. Which ones?

Mr. JOHNSON. I'm not at liberty to give you much in the way of details, but I can assure you that we are investigating virtually all of those devices and many others.

Mr. LANCASTER. Have you brought any Federal prosecution against any device?

Mr. JOHNSON. We have a court date for a case in Florida on ozone generators, yes.

Mr. LANCASTER. That is the only case that you have prosecuted?

Mr. JOHNSON. That is the only case that we have——

Mr. LANCASTER. How long have you had this act in effect?

Mr. JOHNSON. The 1990 act? Since 1990.

Mr. LANCASTER. When in 1990?

Mr. JOHNSON. November.

Mr. LANCASTER. So, you have had about 15 months.

Do you have any other cases that you are preparing for indictment at the present time?

Mr. JOHNSON. Yes.

Mr. LANCASTER. How many?

Mr. JOHNSON. I can't give you a specific number.

Mr. LANCASTER. Is it fewer than 10 or more than 10?

Mr. JOHNSON. I can't tell you that. It could be; it could be more than 10; it could be fewer than 10. It depends upon how——

Mr. LANCASTER. Are you head of this agency?

Mr. JOHNSON. Of the Food and Drug Administration?

Mr. LANCASTER. No; of the devices.

Mr. JOHNSON. No; I am head of the department, or the Office of Compliance.

Mr. LANCASTER. But under that comes compliance with the device's statute. Is that correct?

Mr. JOHNSON. That is correct.

Mr. LANCASTER. I would assume that you are the one directing the effort with regard to fraudulent devices. Is that correct?

Mr. JOHNSON. Ultimately responsible, yes.

Mr. LANCASTER. You can't tell me how many cases you have under investigation and how many you are preparing for indictment?

Mr. JOHNSON. No; I can't.

Mr. LANCASTER. Is there someone in your office who can?

Mr. JOHNSON. I don't think so. That may sound confusing, but you need to understand that many of these cases are being developed through the grand jury process with the Department of Justice.

Mr. LANCASTER. But your office, I assume, would have the responsibility for coordinating these efforts.

Mr. JOHNSON. Not all; some of them, yes. We would know about some of them. Some of them are being operated and managed by the Department of Justice after referral has been made by us, and they may generate a number of actual actions.

Mr. LANCASTER. How many actions have you referred to the Department of Justice? Can you give me that figure?

Mr. JOHNSON. Off the top of my head, no; I cannot.

Mr. LANCASTER. Can you provide that for the record?

Mr. JOHNSON. I sure can.

Mr. LANCASTER. Would you provide that for the record?

Mr. JOHNSON. Yes; I will.

Mr. LANCASTER. Could you also provide for the record any cases, not necessarily the case itself, I understand the sensitivity of that, but the number of cases that you have under active investigation, and, second, the number of cases that you have in preparation for presentment for indictment?

Mr. JOHNSON. Yes.

[The information was not received.]

Mr. LANCASTER. Thank you, Mr. Chairman.

Chairman WYDEN. Well, thank you all very much. Your testimony was very helpful. Let me start by asking some questions of you, Mr. Johnson, if I could.

On page 6 of your testimony, you state that to further combat medical fraud, FDA has established a toll-free telephone line. Now my staff in the last few days has anonymously called the FDA toll-free phone line to find out specifically how a citizen might proceed with questions about a product or service a questionable promotional activity, or a questionable device.

The FDA phone bank told my staff that they would have to talk to at least four different people and the only specific advice that we were given involved a suggestion from the FDA phone staff that we call a local health official, a local county health official. This doesn't seem to me to be a very effective way to proceed. Does it to you?

Mr. JOHNSON. From your description, it certainly does not. I think that phone line was set up primarily for health professionals to seek information and report fraudulent or questionable promotions of drugs, devices, and what-not.

Chairman WYDEN. Well, what I would like to do is, I would like to have staff give you the specifics on this particular case, and I would like you all to report in writing whether this is an exception to the way things are supposed to work or more serious evidence for this toll-free line not working. As you know, in another part of my life, I sit on the Energy and Commerce Committee where we have statutory jurisdiction over the FDA and have been in several hearings with Dr. Kessler talking about new efforts to address problems in devices—I found those comments very encouraging both in terms of his commitment and his agenda for the future. But they seem in conflict with what our phone call revealed.

It is very hard to square what Dr. Kessler has said and what Dr. Kessler obviously wants to do with our investigation, because it is quite clear that he is sincere, but to hear from people like Mr. Everitt who is an investigator, a criminal investigator, out in the field, in Idaho,—there seems to be a pretty big gap between what is hoped for in Washington, DC, [in the Commissioner's office] and what is actually going on out there on the ground with Mr. Everitt at the local level. I want to ask you about a couple of those problems.

Now, Mr. Everitt, in response to my question, said that he felt that FDA warning letters were, in effect, tipping off quacks and questionable practitioners in a fashion that they were able to take those warnings and slip out of the grasp of local and Federal law enforcement officials. What seemed to trouble him most is that not only is the national office of FDA not doing enough to help him, but that these warning letters tip-off the bad guys and allow them to find a safe sanctuary somewhere else.

Are you troubled by what Mr. Everitt has just told us this morning, and, if so, what does the agency plan to do to turn that around?

Mr. JOHNSON. I think that gets to what I had tried to express in the beginning. Some of the comments that he made about investigational strategies and techniques are lessons that we have learned, and indeed we are concerned, as he is, about telescoping our intentions, and while warning letters or communications may be appropriate in certain situations, in many, when you are dealing with health fraud, particularly clinics, is not a very effective way because it does tip your hand, and, in fact, we avoid using them in those situations.

Chairman WYDEN. Do you plan to use fewer warning letters in the future?

Mr. JOHNSON. I think clearly we are making searches, criminal searches and seizures. We don't send warning letters when we come to make a criminal search and seizure.

Chairman WYDEN. Well, my understanding is—I believe it was one of the cases that we talked about today and mention was made of the seizures—there were warning letters sent, and by the time the seizure was actually implemented a lot of the fraudulent devices had been moved down the road.

Mr. JOHNSON. I think you may be referring to the Paradise Pain Clinic. Warning letters weren't issued to the Paradise Pain Clinic. I think the reason why those devices got away was that we obtained an inspection warrant because we anticipated that we would not get a cordial welcome. At that time, when we went in and made that inspection, we authorized the field investigators to administratively detain the devices pending processing of a seizure through the Justice Department. That seizure was delayed in the U.S. Attorney's office and was not filed and executed within the timeframe of the administrative detention, and so some of the devices were secreted away by——

Chairman WYDEN. But this just again illustrates that the system doesn't work. Isn't that correct?

Mr. JOHNSON. Yes; obviously, we did not seize the devices we wanted or all of them.

Chairman WYDEN. So, we have got a case of the system not working very well. You have told us that there would be fewer warning letters in the future, and that seems to me to be a constructive step. I think that the next area that I wanted to ask about was the matter of Mr. Everitt saying that he felt that the Federal Government is always just a little bit late and after the fact, and I note that on page 2 of your testimony your Cincinnati district office talks about the destruction of several thousand—2,000—pairs of eyeglasses involved in some kind of questionable claim.

Now my understanding is that at the same time this destruction was taking place—these 2,000 pairs of eyeglasses—there was a TV infomercial being run for a different company which made almost the same kind of product and claims—a very, very small difference—and that infomercial had been running for many, many months. The evidence we have been able to pick up indicates that many more times the number of glasses were being sold this way, then were being destroyed in Ohio, and those people got off and were able to slip through the system.

Now is this troubling to you, and, if so, what is being done to address this kind of situation?

Mr. JOHNSON. Well, I think clearly it is troubling from the standpoint that we are not being as effective as we would like to be, comparing sheer numbers. We have a number of actions on pinhole glasses—we have a number of actions in process, seizure actions and criminal investigations. In fact, the voluntary destruction was the result of a threatened action on our part. But there are other actions as to pinhole glasses. I don't know whether they are related to the infommercial that you are speaking about. There are other actions in the mill. We have taken previous actions as well.

Chairman WYDEN. Well, I don't question the value of the actions that you are taking, but it seems to me that there are two things at work here. There are an awful lot of bad guys who are still out there because for some reason there does not seem to be a clear, coordinated, campaign. Even in the case of the Paradise Clinic, we saw what happened when things broke down between your office and the Justice Department, and it seems to me that until we have strong, clear campaign, there is not going to be much of a deterrent out there against these bad guys. As a result, you all come to congressional hearings and talk about destroying 2,000 pairs of glasses, and my constituents and others come to people like me and talk about infomercials and marketing techniques where people sell thousands of times that many glasses and get away with it.

We are going to make some real changes, it seems to me, in what is going on. I think that Dr. Kessler unquestionably has good intentions, but when Mr. Everitt comes in and tells us about what goes on in the real world and talks about the need for such things as a central system where the FDA gets information out to the States and where the FDA is more proactive, where Mr. Everitt talks about the problems of a breakdown in these investigations between the regional office and the Federal office, we are going to have to make some changes out there not just in terms of the Commissioner's intentions which I unquestionably agree are sincere and good.

I think I would like to ask you, Dr. Renner—you go to all these conventions and see all these questionable products discussed, marketed, and the like. Does the word get out from these conventions to the FDA, or does the FDA send people to some of these conventions every once is a while?

Mr. RENNER. Yes; the FDA has actually raided some of them. There was one here in Washington, DC, that I think they made rather extensive raids.

Every once in a while when I am there, depending on how I'm dressed, they will ask me if I'm with FDA, and I'll say, "Do I look like I work for FDA?" or something like that. The group is very suspicious. I know that many FDA people have been there, and I know they have taken action because they collect this information to see what kind of sales pitches are going on.

Chairman WYDEN. Well, that sounds constructive, and I am glad to hear about that.

Now, Mr. Reyna, tell me what you would like to see the Federal Government do to get a better handle on the problem. I share your view about the problem of preemption. I think you might be aware that we have been working with the States' attorneys general on a number of questions—the ability of attorneys general to be able to move in Federal court when it seems that the Federal Government has been slow. So, I have considerable sympathies for what you are saying and want to give you an opportunity to outline anything additional that you think that the Federal Government can do to get a better handle on it.

Mr. REYNA. Well, if you had had this hearing a few months ago, I probably would have given you a pretty bleak picture of the cooperation between the States and the FDA. Even though we considered them our regular working partners, some of the problems you have just mentioned such as the regulatory letters, it was not unusual for us to be investigating a case and find a company send us as a defense a regulatory letter that they had gotten and then nothing ever happened to them as a result of having gotten it.

It was not unusual for us to approach the FDA regarding getting testimony or affidavit testimony, which they are allowed to give under the statute, simply regarding the facts contained in a regulatory letter to find out that they had an administrative position against supplying us with that evidence we needed to proceed. So, things were in pretty bad shape.

Currently, we do have a cooperative effort. I feel that the FDA message system, which is fairly sophisticated—we get faxes from them several times a day regarding drug warnings, device seizures—is a big help in that regard. Our committee in the National Association has expressed to the FDA that we are willing to take these cases on, investigate them, take investigative work from the FDA, and turn those matters into prosecution. What we need to do is get those cases. We could use the statute to bring actions directly under the Federal Act, and we could use some guidance in getting some of the States that don't have a model act up to speed in bringing prosecutions.

One thing that the FDA could really use is some authority to go after false advertising. When you talk about the infommercial situation, it has been particularly frustrating to us. You cannot get the FDA to tell you that a television show claiming it can grow hair on the human head is a false drug representation, because they say that is the purview of the Federal Trade Commission to take action against that commercial. That is the only reason that product is sold. That is a phony health claim. We should be able to go after that product; we should be able to get testimony from the FDA to back us up in going after those products.

Chairman WYDEN. At a minimum, the Federal Trade Commission and the FDA ought to have a clear strategy as to how they are going to fight infomercials that peddle health quackery. It is pretty clear that that is not in place.

Mr. REYNA. The significance is that if those are phony health claims, the burden is on the person selling the product to substantiate the effectiveness of the product. The Federal Trade Commission, on the other hand, has the burden of proving the product doesn't work. That is a much higher burden. They move much more slowly, and their administrative remedies are not what is needed in this area. These are multimillion-dollar scams.

Chairman WYDEN. Mr. Johnson, one other area I am concerned about is, I have heard officials from the Justice Department and elsewhere talking about how more fraud is essentially being perpetrated by cartels. There has been one recent article quoting Justice Department officials talking about how this is not just one doctor, one supplier any longer, but it is cartels. What is the FDA doing, again, in conjunction with other Government agencies, to go after these cartels which seem to, again, be part of the very different trend in health fraud than we have seen in the past?

Mr. JOHNSON. I think, again, getting back to the strategy that we are trying to use now on health fraud, and that is, we think that prosecution is the tool, criminal prosecution, and in doing that we find it is not just one doctor, it is not just one manufacturer, it is, in fact, a conspiracy of a number of people. We have nationwide investigations going on under the authority of grand juries, and we are expecting positive outcomes.

Chairman WYDEN. Are your investigators specifically spending more time on cartel fraud, given the fact that we are seeing more of that and less of the individual doctor/individual supplier problem?

Mr. JOHNSON. I don't have precise figures, but I would have to say probably yes, simply because the major investigations that we have underway now are of that type.

Chairman WYDEN. I would like to have you get back to me in writing on that as well, because I'm concerned that we identify the trends and try to get out in front of this as early as possible on the trends and not just constantly be playing catch-up ball.

[The information was not received.]

Are you concerned, Mr. Johnson, representing the FDA, and Mr. Reyna, representing the States, that insurance companies have not been as forthcoming as they should in terms of letting your agencies know about the health fraud and fraudulent activity?

Mr. JOHNSON. I'm not sure that I can make a categorical statement. We have, on occasion, run into problems where information would have been valuable to us had it been available and for policy and legal reasons it has not been forthcoming. I can't characterize it for you as a major problem. It has become a problem. We have encountered it. I don't know that it is a major problem, and it may be only that we have just not had occasion to need that information.

Chairman WYDEN. Well, we have been told by a number of investigators that this is a very serious problem, that insurance companies—and, let's face it, third-party payers, public and private—pay a big part of the bills in this country, and if you don't think this is a problem, I have to tell you, I think that it is. Again, its another one of the trends that we are not out in front of. We have got to get that information from insurance companies, because they are seeing it a lot earlier than some of your folks are.

Mr. JOHNSON. Well, I think in individual cases yes, clearly, it has been a major problem for individual cases. In other situations we have gotten cooperation from insurance companies, have gotten valuable information.

Chairman WYDEN. Why not have FDA and other relevant Federal agencies sit down with the insurance companies and work out clear agreements that are consistent with the laws and the rules that must be followed for getting this information as soon as the insurance companies get it? Why not do that and try to get out in front of this problem rather than constantly be dragging along behind?

Mr. JOHNSON. I think that is a wise suggestion. Our experience is that the insurance companies frequently are not aware of the billing practices and what-not. We usually bring it to the insurance companies' attention that they are being duped or that they are being billed for things that didn't occur or they are being billed falsely for procedures that were not done in lieu of fraudulent procedures at the time.

Chairman WYDEN. Mr. Reyna.

Mr. REYNA. We are getting the information. We have to phrase our requests in a law enforcement posture. The insurance companies have been sued under the RICO statute for sharing information regarding health frauds, so they are hesitant to be forthcoming. They have also been hit with very large bad-faith judgments for quack treatments, and some of them question whether they should even be conducting fraud investigations at all, whether or not that just leads to even larger judgments coming against them.

So, some of them are a little snake-bitten. Some companies are very active in pursuing health fraud; some are not active at all, and that is a problem. They should be required to be active in pursuing health fraud and in supplying that information to us.

Chairman WYDEN. You are darn right they ought to be required. I mean that is the way you pay health bills in this country; you pay it through insurance companies. We ought to have a clear agreement between Federal agencies and State law enforcement agencies for getting this information, and if it takes changes, for example, in the RICO statute, we need some recommendations for doing it. But this should not be some kind of isolated situation: "I hope we get it from the companies." Those are the people who are paying the bills, and I think that a number of our Government GAO reports are going to have some more to say about this issue in the very near future. To me, this is something that cannot be minimized.

Dr. Renner.

Dr. RENNER. For the last 5 years, there has been an association of insurance companies called the Anti-Health Fraud Association. They have training sessions, but, as you said, it is spotty from one company to the other.

There is evidence that quacks have formed insurance company brokerage billing services, and they are starting to become more aware of that. Recently, we found out they had set up their own 800 hotline, quote, to report health fraud. So, they had a way of finding out who was turning people in for health fraud. They have done even double stings.

Some of the quacks are a lot more sophisticated than any of us have ever given them credit for. These are criminal minds that spend full time, and I think we need the resources of the insurance industry to be a part of the solution to this problem, and I think you have hit on a really important aspect of this, because they obviously need this kind of activity.

State licensing of professionals also is another very important thing to coordinate with, and because there is such a variety of State laws, that is a major area to go after licensed health professionals, and they need to be brought into this family, too, not just the Office of the Attorney General, but the State licensing people.

Chairman WYDEN. Mr. Johnson, I would like you to get back to me with the agency's official position on what is going to be done to coordinate with insurers a program to get information that they may have about fraud and questionable medical practices to your agency and others. It seems to me, if you start this by ringing up the Health Insurance Association of America, which is the association which speaks for the insurers, and talk to them about how this kind of information could be shared, and if you all think that there need to be changes in the statutes, as I think Mr. Reyna touched on. Let us know, because we certainly don't want people prosecuted for doing the right thing.

But a program of sharing this information has got to be something that is clearly defined and a high priority and not just some kind of, "maybe it happens/maybe it doesn't" kind of situation.

The only other question I had—and perhaps all of you would have a comment on this—I said in my opening statement, and we have heard it several places—it has been reported, we have heard it from investigators—that as claims are processed electronically, and we have been given information there were something like 4 billion health claims prosecuted last year, that this has also caused other problems for investigators, particularly that the old paper tracks aren't out there any longer. What is being done to try to figure out a way to generate new leads that keep up with the times? I mean the paper used to be the lead evidence over the last couple of decades. We are not going to have those leads in the future. What is being done to try to address the fact that that information isn't out there any longer?

Mr. Renner. If it is a licensed professional, there is still a paper record legally kept. It may be a computerized record, but the record is still there for eventual evidence, and those records can be requested or demanded or seized or whatever, but some quacks who do things in a hit-or-miss area will—if they keep records, they are going to keep fraudulent records that would justify what they are doing, but many of them, as you know, do it verbally. Licensed professionals you can get at. I think the quacks are going to be harder to get at, no matter what kind of a record system they have.

Mr. Johnson. To the extent that even some of the quacks have become sophisticated, rely on computers, and in many of our searches and seizures we have, in fact, seized the computers, and we have developed some software, some computer skills, to go into those data bases and pull information out.

Mr. Vince. I would add to that, Mr. Chairman, that I believed you categorized your other license on the other committee that has some interest in the agency's activities. I believe you are aware that we have begun implementing our Office of Criminal Investigations. Several of those members are on staff already. We are beginning to build our field force, and as part of that training for the 100-plus criminal investigators that the agency will have out conducting investigations, a substantial part of their interest and training will be in computers, information management, data processing, the technological aspects of the new age of investigation, so to speak.

Chairman Wyden. Well, why don't you, as part of that request that I made, Mr. Johnson, to get your response to the possibility of working with the insurers to share information about health fraud—why don't you include in that a description of any efforts the agency plans to make in terms of using computers and electronic information gathering as a tool, because this is something we have heard consistently, and, no one wants to go back to the old days and having, snippets of paper around for health bills, and I personally thought that what Dr. Sullivan had proposed in terms of the insurance summit with the insurance companies made a lot of sense in terms of coordinating billing, but it seems to me that as we do this and put more and more into these computers, we have got to recognize we are going to have fewer and fewer snippets of paper behind, and somehow we are going to have to figure out how to get the leads and jump start the process.

So, if you could include in your description about how you might use the insurance companies more comprehensively to get information about fraud, your assessment of how we could deal with this electronic blizzard of information and use it to get leads to find the fraud, that would be helpful.

You all have been patient. These are issues that are going to take a lot of this subcommittee's attention, and I hope my colleagues in the Congress. I hear an awful lot of speeches in this country about health care reform, and whenever I hear one of these speeches, it seems to me it ought to start by saying that one out of every $10 dollars is being frittered away to ripoff artists and people who are perpetrating scandals and cheats. You are doing awfully important work, and we will work very closely with all of you in the days ahead.

Would any of you like to add anything further at this point?

OK, the subcommittee is adjourned.

[Whereupon, at 12:45 p.m., the subcommittee was adjourned, subject to the call of the Chair.]

APPENDIX

OPENING STATEMENT
HON. RON WYDEN

BEFORE THE SMALL BUSINESS SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES AND ENERGY

QUACK MEDICAL DEVICES AND PROBLEMS IN STATE AND FEDERAL CONSUMER PROTECTION EFFORTS TO GUARD THE ELDERLY

April 9, 1992

Today, the Small Business Subcommittee on Regulation, Business Opportunities and Energy joins the Aging Subcommittee on Health and Long-Term Care to examine the rising tide of untested, dubious and patently fraudulent medical devices marketed to vulnerable American consumers.

> We are most concerned with the sometimes devastating impact the latest brands of snake oil have on the elderly.
>
> Specifically, the subcommittee's investigation has found that healthcare fraud is a mushrooming, high-growth industry, expected to cost this nation $70 billion this year, and as much as $100 billion by 1995.
>
> One of every ten healthcare dollars now ends up in the pcoket of a quack, a cheating healthcare professional, or with the maker of a dubious drug or device.

By 1995, the healthcare fraud tab will be greater than the total take attributed to organized crime, and there are trends at work that could propel it significantly higher.

During the 1980s the evidence shows that healthcare fraud grew at an astounding rate. Eight years ago, the Pepper Report issued by the late Aging Committee Chairman Claude Pepper concluded that $10 billion was the annual loss due to quackery perpetrated in hundreds of clinics throughout the United States and Mexico. The Pepper Report said then that rooting out healthcare fraud was a low priority, and there's not much to contradict that conclusion, today.

There are a number of specific reasons why healthcare fraud is growing at such a horrific rate, and the chair will outline a few them:

> The crooks have gotten greedier and smarter. They circunmvent federal drug laws by inferring unfounded, medication-like effects for products marketed as nutritional supplements. They write promotional brochures for electronic "black boxes" in words of legal art so that they can claim that in writing they have no human medical use, and them pitch them verbally as cancer cures to individual patients.

Here's an example:

This is a Sweep Pulse Resonator. The subcommittee got this from the Idaho Attorney General. It was seized in a raid on a clinic in Twin Falls.

This box was promoted by its inventor as a device which would cure just about anything -- cancer, arthritis, AIDS. The list goes on and on.

And this is how it works.

A little bottle of water and alcohol goes into this hole. The practitioner then connects the patient to the box via an electronic "lead." Unique patient information is fed into the box. The patient is told that this will "electronically calibrate" and "charge" the solution of water and alcohol.

The patient then drinks the solution over a period of time, or rubs it on his skin. Once the medication is used up, the patient doesn't even have to go back to the clinic, and the machine, for more. Just send in a personal photo. It's placed in the machine's crevice, along with the solution, and the little charger does the rest.

The FDA never bothered to go after this practitioner. Even though they were being sold nationwide for as much as $2,000, each. When Idaho state authorities raided the clinic they found about 200 devices.

Federal fraud investigators have told the subcommittee that there are other forces at work driving the health fraud menace:

-- While most doctors are honest, too many overcharge for procedures, or bill for services never rendered; quack device manufacturers are promoting and marketing electronic cures for cancer or AIDS; some distributors of legitimate medical and health equipment sucker unsuspecting consumers to buy unneeded supplies.

-- Scam artists can move quickly to escape investigation and charges. Sometimes they operate from mobile laboratories or clinics. Often, their quack practices or fraudulent device sales are organized in several states, allowing the scam kingpins to jump from one jurisdiction to another, always one step ahead of the law.

-- Prosecution of these cases for financially strapped state authorities is expensive and uncertain. Some jurisdictions won't take cases involving losses of less than $200,000, letting many a cheat skip town or change their modus operendi.

-- Unwillingness of insurance companies to share practitioner billing information allows for insurance reimbursement fraud on a broad scale.

-- Direct-mail promotions and 900-number telemarketing campaigns gin-up this torrent of snake-oil sales.

Charlatans are using state-of-the-art technology and a new wave of marketing ploys to ply their trade. While government seems to be in the regulatory Dark Ages, the crooks take advantage of poor coordination between federal agencies, and their state counterparts, jurisidictional gaps, and the general sense that healthcare fraud is not a priority.

Even though the Food and Drug Administration has told the subcommittee that the healthcare fraud industry is "alive and thriving," our federal watchdogs don't seem to have the same level of vigour.

Enforcement agencies and insurers must develop a coordinated game plan to fight this fraud by sharing information, techniques and even personnel, or the more sophisticated scams will continue to grow. Without this strategy, more and more Americans will be ripped-off, demeaned -- even driven to an early death -- by these health fraud privateers.

This strategy must focus on a way to cut through the electronic blizzard of claims filed in a computer age. We estimate that as many as four billion separate pieces of billing information are processed each year, creating new opportunities for fraud. The traditional paper trail has been lost, and fraud investigators have fewer documented tracks to follow.

This subcommittee's investigation into out-patient healthcare shows that the lack of peer review and established standards creates a fertile field for the quacks and cheaters.

Finally, the chair observes that as this country debates healthcare reform, the government ought to make clear that before citizens are taxed more for healthcare, the federal government should ensure that the more than $800 billion spent this year is spent well.

As Sherry Spencer, one of our witnesses today, will say in describing her family's fatal experience with healthcare snake oil:

"No family should have to go through what my family has."

No government should nod and wink at fraud which rips-off and even kills consumers. Fraud investigation and enforcement efforts are dangerously inadequate, and this subcommittee will be working to set in place a new, stronger system that can turn this problem around.

FOR IMMEDIATE RELEASE
THURSDAY, APRIL 9, 1991

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STATEMENT OF
THE HONORABLE EDWARD ROYBAL, CHAIRMAN, SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE OF THE U.S. HOUSE SELECT COMMITTEE ON AGING ON

"UNPROVEN MEDICAL DEVICES AND THE ELDERLY"

LADIES AND GENTLEMEN. MEMBERS OF THE SUBCOMMITTEES. FIRST, I WOULD LIKE TO THANK MY DISTINGUISHED COLLEAGUE FROM OREGON FOR JOINING ME IN CALLING FOR THIS HEARING -- THE FIRST IN A SERIES OF HEARINGS WE WILL BE HOLDING TO EXPLORE THE NATURE AND EXTENT OF QUACKERY AND ITS IMPACT ON OUR NATION'S OLDER AMERICANS.

IN 1984, THE LATE CHAIRMAN OF THIS COMMITTEE, CLAUDE PEPPER, ISSUED A REPORT ON QUACKERY WHICH CONCLUDED THAT BILLIONS OF DOLLARS -- $10 BILLION ANNUALLY -- IS LOST TO PHONY MEDICAL TREATMENTS AND PRACTITIONERS. THE PURPOSE OF OUR CURRENT INQUIRY IS TO SHOW HOW MEDICAL FRAUDS AND FRAUDULENT PRODUCT MARKETING TECHNIQUES KEEP UP WITH THE TIMES. AIDS WAS NOT THE NATIONAL EPIDEMIC IT IS TODAY, AND NOT SURPRISING WE HAVE FOUND THAT PHONY CURES FOR THIS DEADLY DISEASE ARE NOW FREQUENTLY TOUTED BY THE PROMOTERS OF BOGUS CURES. NEWSPAPERS AND MAGAZINES WERE THE PRIMARY VEHICLES FOR ADVERTISING PHONY PRODUCTS AND CURE-ALLS OF YEARS PAST. TODAY, ADVANCEMENTS IN TECHNOLOGY HAVE MADE IT POSSIBLE FOR MANY OF THESE QUESTIONABLE PRODUCTS TO BE SOLD BY TELEPHONE OR THROUGH TELEVISION WITH THE ADVENT OF INFOMMERCIALS.

SADLY, FEDERAL AND STATE REGULATORY EFFORTS DESIGNED TO CRACK DOWN ON THE INCIDENCE OF HEALTH FRAUDS ARE MINIMAL AND HAVE NOT BEEN REVISED TO KEEP UP WITH THE TIMES. ENFORCEMENT OFFICIALS AT BOTH LEVELS ARE FRUSTRATED BY THEIR INABILITY TO EITHER CRACK DOWN ON PHONY MEDICAL PRACTITIONERS IN A TIMELY FASHION OR TO GET ENOUGH DISSATISFIED CUSTOMERS TO REGISTER COMPLAINTS. MEANWHILE, AS TESTIMONY TODAY WILL DETAIL, ABSENT NEEDED FEDERAL REGULATION, PEOPLE WILL CONTINUE TO SEEK CURES FOR THEIR DISEASES IN CLINICS THAT MAY BE UNSCRUPULOUS, WHERE THE CARE RECEIVED WILL NOT NECESSARILY BE SANCTIONED BY THE FEDERAL GOVERNMENT -- WHERE THE DOCTORS MAY NOT HAVE MEDICAL LICENSES, WHERE THE CLINICS AND THE EQUIPMENT MAY NOT BE REGULATED AND SUITABLE FOR MEDICAL USE. WHAT THIS HEARING WILL EXAMINE IS THE ROLE THE FEDERAL GOVERNMENT MIGHT PLAY IN ASSURING THE AMERICAN PUBLIC THAT THE HEALTH CARE THEY RECEIVE IS RENDERED BY LEGITIMATE PROFESSIONALS AND THAT THE DEVICES USED BY MEDICAL PROFESSIONALS TO HELP GUIDE THEIR JUDGEMENTS ARE RELIABLE. UNFORTUNATELY, AS THIS HEARING WILL UNFOLD, WE WILL HEAR MANY TALES THAT SERVE AS EXAMPLES OF GLARING GAPS IN OUR NATION'S HEALTH CARE SYSTEM -- SO DESPERATELY IN NEED OF REFORM.

WE THANK ALL THE WITNESSES FOR BEING HERE TODAY AND WE LOOK FORWARD TO YOUR TESTIMONY.

THANK YOU.

NEWS

EDWARD R. ROYBAL, Chairman
300 New Jersey Ave., S.E., Room 712
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Select Committee on Aging

U.S. House of Representatives

FOR IMMEDIATE RELEASE
APRIL 9, 1992

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ROYBAL ANNOUNCES JOINT HEARING ON UNPROVEN MEDICAL DEVICES; POTENTIALLY DANGEROUS "REMEDIES" BILK ELDERLY OUT OF MILLIONS ANNUALLY AND CAN COST THEM THEIR LIVES

(WASHINGTON, DC) -- Congressman Edward R. Roybal (D-Calif.), Chairman of the House Select Committee on Aging and its Subcommittee on Health and Long-Term Care, today announced a hearing on unproven medical devices and the elderly. This session, to be held jointly with the Subcommittee on Regulation, Business Opportunities and Energy of the House Committee on Small Business (Cong. Ron Wyden, D-Ore., Chairman), will take place Thursday, April 9, 1992 at 9:30 a.m. in Room 2359-A Rayburn House Office Building.

"Health fraud in all its forms costs American consumers and insurers an estimated $80 billion a year," said Chairman Roybal. "Unfortunately, the unscrupulous people who market quack products see the elderly as easy marks for their 'miracle' remedies," said Mr. Roybal. "Many seniors have chronic conditions, such as cancer and arthritis, and are eager for relief."

The hearing, the first in a series on health fraud, will focus on the use and regulation of unproven and potentially dangerous devices; what State and Federal regulations, if any, govern the sale of these devices; and the track record of State and Federal enforcement agencies in their attempts to combat medical device quackery.

"Although the number of complaints regarding untested and unproven medical devices has skyrocketed," said Chairman Roybal, "enforcement efforts remain weak. This hearing will show us what the Federal government needs to do to fight this life-threatening form of fraud."

"One of our witnesses, an Idaho woman, has a tragic story to tell," noted Cong. Wyden, who will chair the hearing. "Her mother was 'treated' for cancer at a Las Vegas clinic and died after relying exclusively on the clinic for treatment. The clinic owner has no medical credentials and no documentation of the effectiveness of his experimental machine."

The Subcommittees will hear testimony from victims of device quackery; a representative of the Texas Attorney General's office; experts on quackery; and a representative of the Food and Drug Administration.

STATEMENT OF MATTHEW J. RINALDO
JOINT HEARING
BEFORE THE SUBCOMMITTEES ON HEALTH AND LONG-TERM CARE AND REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY

April ~~8~~, 1992
9

Mr. Chairman, I commend you and Chairman Wyden for calling this hearing to examine the alarming problem of fraud and quackery in health care. In 1984, the Subcommittee on Health and Long-Term Care determined that medical quackery cost Americans nearly $10 billion. While we lack a clear picture of the current scope of this problem, recent investigations have indicated that the economic cost of this fraud now far exceeds that figure.

Frankly, this problem distresses me greatly. I am dismayed by the fact that an multi-billion dollar a year industry preys upon the pain and fear of older Americans. Of course, this is not a new issue. Hucksters have always pitched miracle cures and tonics to ease the pain of aging or chronic diseases. But with medical science pushing the boundaries of health care with new research and innovative treatments, it often becomes nearly impossible for patients and their families to determine the validity of extravagant claims.

Not only does medical quackery confuse and exploit our most vulnerable population; it also costs the United States billions of dollars each year in wasted health care spending, money which could be spent providing essential long-term care services or primary care to those most in need. Instead, this money is swept into an underground economy of deceit and greed.

I am also very dismayed by the ineffectiveness of federal law regarding these devices and treatments. Since the law only regulates the health claims of products and devices, the huge loopholes allow fraud to go almost unchecked. And enforcement agencies have found that the operators of these fraudulent businesses are highly skilled at evading the legal system.

The charlatans and snake-oil salesmen may promise revolutionary treatments and new cures, but their real product is deception and disappointment and, far too often, death. These scams must be ended and the perpetrators of this fraud must be punished, because the suffering they promote is unconscionable.

I look forward to the testimony of our witnesses and to working with my colleagues to close these loopholes and put the miracle cure charlatans out of work once and for all.

OPENING STATEMENT OF THE HONORABLE RALPH REGULA, 16TH - OHIO VICE-CHAIRMAN, SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE

APRIL 9, 1992

MR. CHAIRMAN:

TODAY, THE SUBCOMMITTEE WILL REVIEW WHETHER STATE AND FEDERAL CONSUMER LAWS ADEQUATELY PROTECT OUR ELDERLY CITIZENS FROM FALSE, DECEPTIVE, AND MISLEADING HEALTH CLAIMS CONCERNING MEDICAL DEVICES. A SIMILAR HEARING WAS HELD OVER EIGHT YEARS AGO.

THE FINDINGS OF OUR SUBCOMMITTEE INDICATE THEIR CONTINUES TO EXIST A VERY SERIOUS PROBLEM. IN FACT, THE ISSUE HAS GROWN WORSE SINCE FIRST INVESTIGATED BY THE SUBCOMMITTEE.

HEALTH FRAUD NOW COSTS AMERICAN CONSUMERS AND INSURERS NEARLY $80 BILLION ANNUALLY. THE ELDERLY ARE OFTEN TARGETED BECAUSE OF THEIR CHRONIC NEED FOR MEDICAL SERVICES. IN 1984, THE SUBCOMMITTEE ESTIMATED THAT OVER $10 BILLION OF THE HEALTH-RELATED CONSUMER FRAUDS ARE OF THE TYPE COMMITTED ON THE ELDERLY. LEADING MEDICAL QUACKERY EXPERTS WILL TELL THE SUBCOMMITTEE TODAY THAT THE DOLLAR AMOUNT NOW FAR EXCEEDS THAT FIGURE. A SPECIFIC FIGURE IS DIFFICULT TO SET BECAUSE NO

FEDERAL OR STATE AGENCY CURRENTLY MAINTAINS SYSTEMATIC OVERSIGHT OR CONTINUED MONITORING OF THE PROBLEM.

MOST QUACK DEVICE MANUFACTURERS ARE ABLE TO AVOID THE DICTATES OF FEDERAL DEVICE LAW AND THE MEDICAL DEVICE APPROVAL PROCESS THROUGH THE USE OF BROAD AND OVERT DISCLAIMER LABELING. FURTHER, THEY RELY ON WORD-OF-MOUTH TESTIMONIALS AND ANECDOTAL EVIDENCE TO PROMOTE AND SUBSTANTIATE THEIR PRODUCTS. THESE CLAIMS ARE SUBJECTIVE AND DIFFICULT TO REFUTE OR DISPROVE.

NEITHER THE FOOD AND DRUG ADMINISTRATION, OR THE VARIOUS STATE AGENCIES POLICING THIS AREA, HAVE HAD MUCH SUCCESS IN

STEMMING THE RISING TIDE OF FRAUD. I NOTE WE HAVE WITNESSES FROM BOTH THE FDA AND THE IDAHO AND TEXAS STATE ATTORNEY GENERAL OFFICES. I ESPECIALLY LOOK FORWARD TO THEIR TESTIMONY AND TO HEAR WHAT IS BEING DONE TO IMPROVE THE PRESENT SITUATION.

AS IN 1984, THIS SUBCOMMITTEE BROUGHT TO THE PUBLIC'S ATTENTION THE PLIGHT OF THE ELDERLY AND MEDICAL QUACKERY. I AM CONFIDENT TODAY'S HEARING WILL ALSO HIGHLIGHT THE ISSUE. HOWEVER, IT IS ESSENTIAL THAT CONGRESS ACT UPON THIS PROBLEM IN A FORCEFUL MANNER RATHER THAN LET IT ONCE AGAIN QUIETLY SLIP FROM OUR COLLECTIVE CONSCIOUS.

THANK YOU MR. CHAIRMAN, I RETURN THE BALANCE OF MY TIME.

STATEMENT OF MRS. SHERI SPENCER
APRIL 9, 1992

Mr. Chairmen thank you for the opportunity to address you this morning on the issue of dubious medical devices and how they are used.

My name is Sheri Spencer. I am a wife and a working mother of four from Boise, Idaho. I am a License-Practical Nurse and I work for four doctors whose help and support during the events I am about to describe has given me the strength and courage to tell my story. I am here to tell you of my family's experience with a questionable medical device and the tragedy that it brought into our lives. I am also here in the hope that something more can be done to insure that what happened to my family does not happen to others.

Last June, my mother died of cancer. She was 54 years old and she left behind a husband, 9 children, the youngest of which was 13, and 15 grandchildren who love and miss her very much. I am convinced that the treatment my mother received from an untested and unproven medical machine contributed to both her failure to seek proper treatment and ultimately her death.

This is her story.

In March, 1990, my mother was diagnosed with a lump in her left breast. My mother had always been suspicious of doctors but agreed to have the lump surgically removed at a hospital near her hometown of Orem, Utah. Prior to her surgery, my mother had been in contact with a medical doctor who practiced various forms of alternative cancer therapies. He told my mother to make sure that the surgeon remove and preserve the lump for further investigation and to make sure that the surgeon did not remove any of the surrounding tissue.

The operating surgeon found a tumor the size of a grapefruit, and he also found that the cancer had metastasized in the surrounding tissue. Nevertheless, my mother rejected his treatment recommendations and returned to her alternative therapy after signing a waiver releasing the operating surgeon from all future responsibility. The alternative therapist took the tumor and made what he called an "anti-serum" from it and began my mother on a course of alternative anti-cancer treatments.

In September, 1990, while my mother was still receiving the "anti-serum" treatments, she met a man named Evens Rapsemanakis from Las Vegas, Nevada who ran a "pain" clinic in Las Vegas, Nevada, where he claimed he cured cancer and other diseases like diabetes. He told my mother that he was not a medical doctor but a scientist and an inventor with a Ph.D. from a Greek University, and that he had developed a "new type of energy and electrical therapy" while working for the McDonald Douglas Corporation.

The energy and the machine that he invented, he said, would entirely eliminate the need for medical doctors. However, when he told McDonald Douglas of his discovery, they fired him. Rapsemanakis also told my mother that the medical profession would have him killed if they knew that he had a device that could cure cancer.

Page Three

Dr. Rapsemanakis, as he called himself, told my mother that in order to treat her, she would have to have a referral from a practicing healthcare professional. He told her to visit a Las Vegas Chiropractor who would formally refer her to his "Paradise Pain Clinic." The chiropractor told my mother that she was a prime candidate for a "heart attack" and referred her to the "Paradise Pain Clinic."

My Mother began a course of treatment at the Paradise Pain Clinic in September, 1990. The treatments, as I understand them, consisted of hooking my mother up to a machine that generated low-current electricity by means of electrodes hooked at various points directly to her body as she sat in a reclining chair.

Mother and I didn't agree on the value of traditional medical therapies, but she always described her treatments to me because of my healthcare background. The night of her first treatment, she was quite upset and called me because, as she put it, "I am bleeding from every place I can." That didn't sound right to me and I encouraged her to go to an emergency room at the hospital. Instead, she called Dr. Rapsemanakis. She told me that Dr. Rapsemanakis told her it was normal and "wonderful" because the energy was going into her system and the cancer cells were "exploding". The first treatment, he told her, always traumatizes the system. She did not go to the emergency room.

My mother started out hooked to Dr. Rapsemanakis' machine for one hour a day, four days a week, with a week off. He charged her

$100 per session, telling her that he was only charging her for the use of the space, the cost of the electricity and for staff time. He told her he was not charging her for his time because she was his "miracle patient" in that he had never before cured so developed a cancer.

The treatments soon expanded to 3 hours a day, 6 days a week. My mother told me she was feeling better but her looks told a different story. I noticed when I visited with her that she had puffy and infected sores on her back where the electrodes were attached. She was rarely at home in Utah and spent long stretches of time in Las Vegas to be close to the therapy. It was also at this time that I noticed that the skin above her right eye had begun to sag.

Soon after, Dr. Rapsemanakis told my mother that he now had to treat her brain, and started treating her above the neck. At this time I thought my mother began acting very differently. Though she said she felt great, she had lost over 60 pounds, she looked jaundiced and seemed confused at times.

I begged her to see another physician because I thought the cancer was spreading -- at one time I had worked for a home health care agency and had taken care of terminally ill patients. She told me that Dr. Rapsemanakis told her that the cancer was now "gone" but that curing her had taken its toll on her body. Soon, they would begin treatments to rebuild her body.

Mr. Chairmen, my mother trusted this man and my whole family wanted her to be happy and well. My urging her to see another doctor caused much pain between us, but I didn't know what else to do and try as I might, I couldn't convince her that she was getting worse, not better.

On April 19th, 1991, Dr. Rapsemanakis called my mother in and told her that she was "completely cured." He told her that she didn't need to come back anymore that she should go home and spend time with her family. My mother told him that she still felt and looked sick. Dr. Rapsemanakis replied that she should be grateful that the cancer was gone but that he couldn't do anything about how she looked.

When she came home, she told members of the family that she felt funny and that she could almost feel things "growing inside." She wanted to go back to Las Vegas for more treatments. She eventually returned to the clinic where she was told that she could have 4 more days of treatment on the energy machine, but that was all. My mother was particularly distressed because they wouldn't give her the full 3 hours of treatment. Dr. Rapsemanakis said that he had too many other patients that needed his help.

When she came home, she continued to feel bad and look bad. Finally, the family demanded that she get a CAT scan, if for no other reason than to prove that the cancer was gone. The CAT scan found that she had a tumor in her skull above her sagging eye, that she had another tumor the size of a golf ball behind the opposite eye, that she had multiple tumors in her breasts, and that the femur bones in her legs had so many tumors that they were mottled. The Oncologist who analyzed the CAT scan told us that there was no hope to reverse the cancers and, after he saw her surgical record, informed us that her cancer was treatable at the time of her original surgery.

My mother soon lost the ability to walk and to talk. In the first week of June, 1991, Dr. Rapsemanakis called to see how my mother was doing. My mother still trusted him, but I was furious. My mother could no longer speak so I talked with him. I told him she had cancer "everywhere" and that he had "done nothing for her." He told me that he had "cured" her and that the cancer might show up on the X-Ray, but that it was dead. He wanted me to put her back on a special diet and to bring her back to the Paradise Clinic so that he could begin the "rejuvenation phase." I told him that I'd never let her set foot in there again and hung up on him.

My mother died of her cancer on June 25, 1991.

I was angry but didn't know what to do. The doctors I work with told me to call the Nevada and Las Vegas Medical Societies. I tried that but nobody knew who I should report to, and in one case the phones were disconnected. Finally, one of the doctors in my office put me in-touch with Dr. William Jarvis in California who is a well known expert on quack medical treatments. Dr. Jarvis put the FDA in touch with me. And, in fact, two weeks ago I was extensively interviewed by the FDA about this experience. I have been told that the Paradise Pain Clinic has been shut down, but Dr. Rapsemanakis is still out there and for all I know could be continuing to "cure" cancer with his machine.

Mr. Chairmen, I am here today because no other family should have to go through what my family has. Even today, we do not all agree. Some in my family are grateful to Dr. Rapsemanakis because they don't think that my mother was in any pain when she died. I am not so sure. This has been hard on all of us, but it has brought us closer together as a family. We are getting better.

In closing, I'd like to say that I've thought about why my mother fell under this man's spell. Traditional medicine isn't perfect and their machines and treatments don't always work either. But I think my mother saw this course of treatment as a way to control her medical destiny. I also think that for the time that my mother was Dr. Rapsemanakis' "miracle" patient he treated her with a special care and gave her hope that she did not find in traditional treatments. I hope that traditional doctors and those working on legitimate alternative therapies might learn something from the fear and isolation that caused my mother to reject their help. I hope you on these subcommittees will help find ways to ensure that my mother's story is not repeated in another family.

Thank you for allowing me to tell my story.

INSIDE

STATEMENT OF ROBERT B. READ, PRODUCER, "INSIDE EDITION"

Mr. Chairmen and members of the Committees, my name is Robert B. Read and I am a producer for the television newsmagazine program, Inside Edition.

I am not in the habit of appearing before government bodies but when I was requested by the staff to appear this morning to highlight one of our investigations, given the public safety issues involved, my colleagues and I decided it was appropriate for me to appear.

Over the years, I have reported on numerous cases of medical negligence, questionable treatments, and outright quackery. Although the potential for physical harm and/or financial loss existed in all of these cases, most were relatively isolated situations... their reach limited to that particular locale or community.

But when reporter, Steve Wilson and I began looking into the Century Clinic in Reno, Nevada last year, we were amazed at the far reaching effects of this one medical practice. We found the large waiting room packed with patients, many elderly, some from as far away as Maine and Hawaii. And they were being treated for everything from alcohol abuse to artery disease to multiple sclerosis.

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Many of the patients swore that this clinic was their only hope... that doctors here could do what none had been able to do before.

But we also heard from a woman in New Jersey who's diabetic husband died after visiting the clinic. She says they took him off his insulin, in favor of their own remedy. And one of our viewers from Nevada, who you'll see in a moment, told us that she and her daughter were misdiagnosed and dangerously mistreated there.

To see if these charges were true, I decided to make an appointment and visit the Century Clinic myself... as a patient. And although my initial exam seemed quite normal, I soon encountered devices and treatments that I had never seen before.

With the committee's indulgence, I would like to show a shortened version of the "Inside Edition" report which was originally broadcast on November 1, 1992.

"CENTURY CLINIC" - Shortened Version

Originally Broadcast on 11/1/91

NATSOT: (Dr Katrina Tang using Dermatron)

TRACK: Consider this thing called a "dermatron". The theory is everything important in your body is hooked up to some specific spot on your hands or feet.

NATSOT: Dr. Katrina: Your heart function is good.

TRACK: And if the reading is over 60 or under 40... you got troubles.

NATSOT: Dr. Katrina "...You have a low thyroid.

SOT: Dr. John Renner, Member National Council Against Health Fraud: This is a silly, inappropriate gadget...

TRACK: The federal Food and Drug Administration charges they are illegal, worthless and a health hazard too. Feds have twice raided the clinic and confiscated all the dermatrons they could find.

SOT: Dr. Katrina: We never claim Dermatron can do everything. Dermatron we use as an indicator before the laboratory tests confirm what Dermatron's finding. We never diagnose people.

TRACK: Consider the case of Connie Anderson. When she and her daughter went to the clinic, they ran the Dermatron and a whole battery of tests on them...and then?

SOT: Connie Anderson: "They said that my daughter had 80-90% blockage in the carotid arteries and I had 70-80%, and if I did not have chelation to clear the blockages out, then we would have a stroke and we would die."

TRACK: What's chelation? It's a therapy that involves flushing your arteries with an amino acid substance sometimes used to clean slag out of dirty boilers...sort of a rotor-rooter service to clear any blockages in your circulatory system. Controversial?

SOT: Dr. Renner: "There are all kinds of physician papers about chelation therapy by major medical groups in his country and it is not an accepted treatment and it should not be given."

SOT: Dr. Yiwen Tang: "We try to use our own patient. If they feel they are not sick anymore, they don't go to the hospital anymore, what other proof do you need besides that."

TRACK:	But it didn't work out that way for Connie or her daughter. After just 4 chelation treatments, they say they were so weak they went looking for a second opinion... and they were shocked to find out...
SOT:	Connie: "Our arteries were clear. There was no reason for us to go through all this treatment because we were not blocked."
TRACK:	They say they paid over $2,000 EACH to be diagnosed and treated for a problem they didn't even have.
SOT:	STEVE WILSON - Reporter: "And how much money are we talking about? Well, the clinic is privately owned so all we can go on is what they tell us. But they tell us the clinic grosses $4 million a year--and almost 1 1/2 MILLION of that is pure profit."
TRACK:	So where do so many patients get the idea medical miracles happen here?
SOT:	Yiven Tang: I really shutter every time I see the word miracle appear. There are no such thing as miracles.

TRACK: That's what they tell reporters...but listen what they told a prospective patient...

SOT: **DR. KATRINA:** You've been brainwashed wrong. We're famous here. A lot of people walk out of here.

TRACK: The "patient" is complaining of being tired all the time... he's got a common complaint... and a hidden camera. He's our producer Bob Read and he shelled out 1,800 bucks for tests inside the Century Clinic, only now he's ready to leave.

SOT: **Dr. Katrina:** Oh no, your heart is blocked!
Read: My heart is blocked?
DR. TERRY: Left anterior hemi-block.
DR. KATRINA: That's an allergy block. You must have tons of allergies.

TRACK: And the news only gets worse!

SOT: **Read:** So am I in danger of a heart attack or something?
Dr. Terry: Oh yeah, with the heart, yes.
DR. KATRINA: With shortage of oxygen and with a heart block, if you have a lot of virus then you open yourself up pretty wide.

TRACK: They claim our producer is afflicted with herpes, salmonella, liver hepatitis, yeast infection, the Epstein Barr Virus,

	and of course the biggest worry: Coronary Vascular Insufficiency... Can they save him?
SOT:	DR TERRY: We will be advising you actually to take intravenous chelation.
SOT:	Dr. Stephen Scheidt: That's absolute quackery It is potentially dangerous. It has never been shown to be helpful and you don't even have the disease. You don't have coronary artery disease.
TRACK:	Dr. Stephen Scheidt is one of the country's most prominent cardiologists. His conclusions are based on a complete examination which included a demanding stress test.
SOT:	Wilson to Katrina: "The other doctor says the man is as healthy as a horse! DR. KATRINA: Because we're using different equipment, different standard of testing. WILSON: Is this patient about to have a heart attack based on what you see in that electrocardiogram report? DR. KATRINA: Based on this one we would never tell him that he's going to have a heart attack.
TRACK:	So why did they tell him that?
	DR. KATRINA: I'm sorry we didn't record this conversation because based on this EKG, is not a heart attack risk, no. WILSON: Let me be real honest, We recorded the conversation and there's no doubt about what you said. It's on tape.

SOT: **DR. KATRINA:** It all depends on the interpretation but one thing that I have to repeat again: We never threaten a patient, we only explain to them what the test results show.

TRACK: Which leaves us still wondering, are all these patients really even sick?

SOT: **DR. RENNER:** If you go down there and they diagnose an illness that doesn't exist, it's very easy to cure that illness eventually.

###

ORAL TESTIMONY (Cont.)

Just one final note, we phoned the clinic yesterday and were told to come on down for an appointment... so it appears it's still business as usual at the Century Clinic.

Thank you.

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April 8, 1992

Grady Forrer
Subcommittee On Regulation,
Business Opportunities and Energy
B-363 Rayburn House Office Building
Washington, DC 20515-6318

Mr. Forrer:

I have been requested to answer the following questions as detailed below:

1. *What has been the recent experience of the State of Idaho with untested and unproven medical devices?*

   The Attorney General's Office has seized many devices that were deemed to be untested and unproven by the Food and Drug Administration. These devices were seized pursuant to search warrants issued in Twin Falls, Idaho as a result of the investigation of James Solomon. Other devices, meeting the same description, were seized from a manufacturer in Buhl, Idaho which were being distributed in thirteen (13) states and two foreign countries.

2. *What successes has Idaho had in prosecuting cases involving these devises and what state laws have been relied upon for these prosecutions?*

   Previous cases in Idaho involving practitioners using hyperbolic chambers and colonics as well as other diagnostic and treatment devices have met with successful prosecution. These convictions, however, were gained by filing charges from Grand Theft By False Promise to Manslaughter. Prior to 1990, all cases pertaining to the illegal practice of medicine were charged under other counts because practicing medicine without a license in the State of Idaho was a misdemeanor. Since that time, however, the legislature has strengthened the statute, providing for a felony conviction.

3. *Please describe the types of devices that the state has seized and how they are used?*

   These devices are described as diagnostic and treatment machines. Some provide electrical charges to the body using frequencies purported to either cure diseases or relieve pain. Others are sophisticated-looking computer systems that purportedly allow the practitioner to diagnose disease with the use of a wand and a skin probe. The computer displays the disease that has been detected and purports to prescribe the correct treatment. Still others require patients to place their feet on metal plates; a small electrical current passes through the plates into the body, allegedly to "balance out" the system and draw out harmful toxins.

4. *What kinds of health care consumers are susceptible to the appeal of unproven medical devices and their manufacturers?*

   Although it is hard to characterize a group such as this, it certainly includes a disproportionate number of low income families, elderly people on fixed incomes and those with terminal diseases. Their motivations include cost saving, the side effects of conventional treatments and the hope offered by "alternative" treatments.

5. *Is it fair to say that many "victims" of quack medical devices do not complain because of an abiding belief in the devices in spite of scientific evidence to the contrary?*

   Probably so. Some also believe that the American Medical Association has conspired against manufacturers and distributors of these devices to protect their own lucrative practices.

6. *How effective have federal efforts to curtail questionable medical devices been? In other words, please address the interaction of your office with the federal Food and Drug Administration -- is the FDA acting quickly enough to effectively halt the proliferation of quack medical devices.*

   In the Pacific Northwest I believe the FDA has been very aggressive in handling regional level cases. When the Solomon case was submitted to Washington, D.C. for enforcement action, the momentum was lost. It has been my experience that FDA will respond quickly at the regional level to local law enforcement requests for assistance.

   I do not believe the FDA can effectively curtail the manufacture and distribution of these devices without experienced criminal investigators with authority to seize evidence and make arrests. Most states are not equipped to deal with this kind of crime. These cases are complex, often multi-jurisdictional and require specific investigative knowledge to successfully prosecute.

7. *What steps should Congress consider to improve federal enforcement efforts against quack medical devices and their manufactures?*

Congress must adequately fund FDA to establish a criminal investigative arm which has the authority to subpoena records and place embargoes on devices before they are placed on the open market. Currently, it is my understanding, that the FDA is primarily regulatory in its approach to questionable devices and that the mechanism for investigations may warn violators that they are under investigation, allowing them to take necessary precautions to evade arrest and seizure. The Food and Drug Administration could also enhance enforcement efforts by reducing the lengthy review time which a case undergoes before any action can take place.

Respectfully submitted,

/s/

RANDALL EVERITT
Criminal Investigator

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TESTIMONY

I am John H. Renner, M.D., a family physician, President of Consumer Health Information Research Institute (CHIRI) in Kansas City, Missouri. A nonprofit organization, CHIRI has as its goals the dissemination of accurate health information and the identification of misinformation and quackery.

I am a member of the Board of Directors of the National Council Against Health Fraud. I am also a Clinical Professor of Family and Community Medicine at the University of Missouri, Kansas City, School of Medicine and an Adjunct Professor of Preventive Medicine at the University of Kansas School of Medicine. I have been a consultant to the Food and Drug Administration on AIDS quackery and have been deeply involved in studying and investigating quackery for ten years. I categorize therapies into the following: folklore, quackery, unproven, investigational, proven.

On a regular basis I talk to consumers, legitimate physicians, quack practitioners, and health cult members.

1. I have information on the following dubious medical devices:
   (1) Live cell (whole blood) analysis, using a microscope, T.V. projector, T.V. monitor, and an instruction book that can supposedly diagnose almost any illness known to mankind. I have heard practitioners say they saw "diabetic cells," "arthritis cells," and even an AIDS virus. The first two do not exist, and it would take an electron microscope to see a virus. These people fabricate results. Ads run for these gadgets regularly in alternative medical magazines. This gadget generates $60,000 a year per practice.

(2) Electronic diagnostic gadgets, some with computer and bizarre instruction books, like Vega, Prophyle, Electronic Acupuncture Voll (EAV), Interro, or Computronix. Some use a "disguised research project" to give the impression of legitimacy. The operators of these machines are M.D.'s, D.O.'s, homeopaths, naturopaths, chiropractors, and lay persons. These people generally find something wrong with the subject being tested, later requiring the subject to take herbs, food supplements, or large doses of vitamins.

(3) Phony Chronic Fatigue Syndrome laboratory tests, even though this can be a real illness.

(4) Phony Osteoporosis measuring tests, using fingertip X-rays mailed in for analysis.

(5) Computerized nutritional questionnaires programmed to give only abnormal results, thereby "requiring" mega-nutritional supplements.

(6) Phony testing of the iris of the eye (Iridology), using a camera and so-called geographic map of the iris, showing areas of the body that supposedly correspond to organs of the body and illnesses. One such quack was busing people to his office and diagnosing "impending health problems" and then recommending herbs and nutritional supplements.

(7) Activator gadget used by chiropractors to show where the spine or pelvis or temporal mandibular joint (TMJ) is out of place. Blue Cross/Blue Shield pays for this one. Workmen's Compensation Insurance also pays for this in some areas.

(8) Magnetic healing devices--small ones from $25 to $1,500 for a magnetic mattress so as to "align" all the cells in the body to a north/south pole.

(9) Hair analysis---using head or pubic hair to diagnose and treat a variety of illness, thereby recommending nutritional supplements to treat the "identified" illness.

(10) Devices used to diagnose or treat illness, depending on the imagination and/or ethics of the practitioners.

a. Urine ammino acid tests
b. Nutritional kinesiology (muscle testing)
c. Pendulum testing
d. Water purification devices
e. Yeast sensitivity diagnosis
f. Ozone therapy
g. Pyramid power
h. Saliva analysis
i. Handwriting analysis
j. Thermography
k. Toftness device
l. Mercury amalgam testing devices
m. Urine probability test
n. Dried blood crystal test
o. Infrared test
p. Weird allergy testing

2. Manufacture and use of untested and unproven medical devices. Devices and gadgets are being developed and used at a dramatically increased rate. This is a growth industry.

3. Cost to the healthcare system from the manufacture and use of dubious medical devices and therapies: Please see table on Estimated Costs of Quackery Devices and Quack Remedies, on the following page.

4. Elderly are targets of quackery and dubious medical devices because:

   (1). The elderly have more chronic illnesses, conditions, and problems like diabetes, sexual potency problems, heart problems, osteoporosis, or cancer.

   (2) Elderly people are more trusting, especially with a health professional.

   (3) The elderly are more isolated and cannot shop around as readily.

   (4) Many elderly people like ordering things through the mail, thereby getting their names placed on numerous mailing lists.

5. Failure to complain about manufacturer and/or practitioners. No one wants to admit they were suckers or have been scammed. The elderly seldom will sign complaints or want their names used due to embarrassment at having been duped.

6 & 7. Regulatory loop holes & Legislative/regulatory action suggested: License to practice a healing profession is governed by state governments. Devices are regulated by the federal government. State licensing boards rarely communicate with the Food and Drug Administration. Only a few state attorneys general offices have large enough staff to investigate adequately consumer health fraud. FDA and some states' attorneys general offices have recently teamed up to go after multi-state quackery activity. A unified approach is needed at the federal level by the FDA, FBI, Postal Service, FTC, the Inspector General & state licensure boards.

ESTIMATED ANNUAL COSTS OF QUACKERY DEVICES AND QUACK REMEDIES
(Some practices employ numerous devices)

Practitioner	Total #	% Quacks or Dubious Practioners	Estimate Total Using Quackery	Dollars Generated Per Practioner	Total Device/Quacker Costs
M.D. Medical Doctors	630,000	1%	6,300	$200,000	$1,260,000,000
D.O. Osteopathic Doctors	50,000	10%	5,000	200,000	1,000,000,000
D.C. Chiropractors	40,000	60%	24,000	200,000	4,800,000,000
Nurses: R.N. Registered Nurse L.P.N. Licensed Practical Nurse	1,500,000	1%	15,000	25,000	375,000,000
Dentist	141,000	1%	1,410	200,000	282,000,000
Veterinarian treating humans			300	125,000	37,500,000
Pharmacist & Chain drug stores	100,000	1%	1,000	150,000	150,000,000
Dietitians	60,000	0.2%	120	100,000	12,000,000
Nonlicensed Psychological Practioner	11,200	90%	10,080	100,000	1,008,000,000
Health Food Store	7,300	80%	5,840	350,000	2,044,000,000
Homeopaths	500	98%	495	200,000	99,000,000
Health Mail Order Gadgets & Pills	50	90%	45	500,000	22,500,000
"Herbalists"	1,000	80%	800	25,000	20,000,000
Clinics Outside U.S.A. Practicing Quackery	25	99%	24	2,000,000	48,000,000
Acupuncturists	1,500	90%	1,350	200,000	270,000,000
Multi-level sales Nutrition products Herbs Weight loss products	500,000	80%	400,000	50,000	20,000,000,000
GRAND TOTAL ESTIMATE					$31,448,000,000

Comments to the Subcommittee on Regulation, Business Opportunities and Energy Regarding Health Fraud Involving Medical Devices from the Office of the Attorney General of Texas

Mr. Chairman and members of the subcommittee, on behalf of the Attorney General of Texas, Dan Morales, I would like to thank you for the opportunity to address this body and answer any questions you may have regarding our state's investigations into health fraud involving medical devices. My name is Robert E. Reyna. I manage the Dallas Regional Office of the Consumer Protection Division of the Office of the Attorney General of Texas.

The Texas Attorney General's Office is currently investigating a number of possible health frauds involving medical devices. I would like today to give you, in response to the committee's request, some examples of health fraud cases we have prosecuted in the area of medical devices. I believe those examples will demonstrate why we consider health fraud in the device area to be a serious matter.

Second, I would like to comment on the steps we are currently taking to improve federal and state coordination in the area of device investigation and how we believe that such efforts are the key to successful prosecution of health fraud.

Third, I would like to express our concern to the subcommittee regarding possible claims of preemption in the area of medical devices.

The most common type of medical device fraud prosecuted by our office is the use of approved medical devices for unapproved uses. An excellent example of that is the prosecution undertaken by our office against companies which marketed the diet patch.

The diet patch consisted of a band aid or bandage which was affixed to the wrist. Purchasers were told that wearing the patch would cause rapid weight loss through the external application of a homeopathic medicine, usually derived from oyster shell. The classic approach to a case of this type would have been to seek an expert determination as to whether weight loss through such a program was possible and also to require substantiation from the promoters of the products for the advertising claims they were making.

A much better method of prosecution of this type of case turned out to request from the FDA a determination whether or not the use of such band-aids or diet patch systems to apply over-the-counter medicines was an approved method of transmitting such a medicine. Upon review, the FDA determined in our case, that a patch system for dispensing even over-the-counter drugs was in fact an unapproved drug transmittal system and held that the effectiveness of such a system would need to be demonstrated and the patch be approved as a transmittal device prior to sale.

The importance of this determination was that a consumer fraud which was rapidly growing to amazing proportions, and was being marketed through the familiar pyramid sales technique, was quickly stopped. Such a scheme makes victims of the sellers of the products as well as purchasers. We were able to move quickly against a purely economic crime, which would not normally be high on FDA's priorities.

One of the characteristics of these frauds is that the perpetrators are looking for some magic element of a product which generates rapid demand. The idea of the transmission and application of medication through transdermal patches is one that caught the public imagination and millions of people were ready both to buy and sell a product which claimed it could cause rapid weight loss without the ingestion of any medication or alteration of a person's diet.

Another type of case we successfully prosecuted in the area of approved devices involved electro-muscle stimulators. These stimulators are approved as rehabilitation devices to restore the strength and activity to unused muscle areas. We were amazed to find that the machines are widely available to lay persons and are advertised to owners of reducing and tanning salons and were claimed to cause weight loss or to reshape the body of a persons too lazy to exercise.

Again, in electro-muscle stimulators we had a type of product which was very alluring to the public and which was causing a great economic loss. The effectiveness and safety of electro-muscle stimulators, as they were being used, had not been demonstrated. By relying upon the approval and labeling requirements of the U.S. Food and Drug Administration, we were able to remove these machines and the promotions which had invaded the weight loss market in Texas, in fairly short order.

An area which is of great concern to us and which we have sought to regulate is a large number of phoney medical diagnostic machines and computers currently being used by licensed and unlicensed medical practitioners of various sorts. These are machines which users claim can diagnose disease by taking some electronic or chemical reading from the body. They also are claimed to formulate chemical or homeopathic remedies which are produced by a computer formula to correct imbalances in the body.

The machines are extremely expensive, costing in the tens of thousands of dollars. They have not been approved and do not bear the proper federal legend. But because they bear the look and complicated nature of legitimate medical testing devices, can be used to charge consumers large amounts of money while promoting the same snake oils and phoney remedies that have always been sold to the gullible. In the case of the diagnostic computers, the computerized look makes these machines look credible to the perhaps slightly less gullible public today.

Our state health department is also on the look out for products which can cause immediate danger to health. We currently have an initiative proceeding investigating the use of silicone injections through a scheme in the Houston area, to charge several thousands of dollars for breast injections directly into the body. This silicone is not incapsulated and is in fact an industrial grade product which can be very injurious to health. The injections are performed by non physicians.

These cases have been accepted for criminal prosecution and pleas entered and jail terms assessed. We have put into investigation many common consumer frauds and have been able to do a better job of prosecution and investigation through cooperative efforts with the FDA and local health departments. A case which might be prohibitive to prosecute as a consumer fraud, when identified as a violation of the Food and Drug Act or our state act, and is identified as posing a potential danger to health, becomes a case which can actually be prosecuted more rapidly and successfully. The shift of burden which takes place with the required drug or device approval, is in many cases, the public's main line of defense from fraud.

Through cooperative efforts of the National Association of Attorneys General, Food and Drug Administration at the urging of Dr. Kessler, our working group monitors on a regular basis any reports of potential health fraud being perpetrated through devices as well as through food and drugs. We feel that our initiative in the area of devices is especially important because the prosecution of economic crimes against consumers is our business in the state consumer protection units.

By the nature of its mission, the FDA is required to prioritize a number of its investigative efforts. Food and drugs by definition have had a higher investigative profile within the area of devices. Mere economic crimes as opposed to immediate risks to health have been the lowest priority in device investigations. I believe that a period of time during which there were limitations in the resources to investigate a fraud in the area of medical devices previously existed. Those limits do not exist at the present time and do not need to exist. Sufficient investigative resources can be allocated, should the states be allowed to prosecute violations of the Food and Drug Act. In Texas, that has proven to be a significantly easier process, since our state has passed a model food and drug act which mirrors the federal act. We are able to move rapidly against these frauds. In fact, the FDA is coming to rely on us to do so.

A matter of extreme concern to us is that the elderly are particularly susceptible to these types of frauds, whether it is the marketing of diagnostics, pain relief devices, tapes which claim they can lower your cholesterol or change the shape of your body, magnets with therapeutic affect that you place in your mattress.

The public needs help in judging which medical devices are valid. There will always be Mr. Art Linkletter hired to claim medical benefits for a reclining chair. There will always be new promotions being aimed at the public, which claims cross over the line and in fact become health claims.

Whatever authority the state attorneys general can be given, they can give priority to these types of cases. Our agencies are ones which, in a good number of states, high priority is placed in bringing public interest cases in areas where public health and safety is involved. We welcome the chance to bring cases against health frauds. We've had a number of significant successes and we feel we will be bringing even more on a regular basis as the FDA comes to look to the states to get rapid enforcement in areas such as this which are tailored for our enforcement capabilities.

Finally, I would like to address attention to the matter of preemption in the device area. The current preemption provision is overly vague, and has resulted in court decisions finding preemption where there should be none.

We believe that there is no need for preemption in this area. On the state enforcement level, we generally coordinate our efforts with FDA to ensure a consistent state-federal approach to a particular problem. Moreover, in those areas where there is an actual conflict between the state and federal scheme, existing constitutional principles of conflict preemption ensure that a manufacturer is not put in a catch-22 situation of having to violate federal law to comply with state law.

If preemption in this area is to continue, we believe Congress should act to clarify just what state laws are preempted. We have two primary concerns:

First, there should be no preemption of state law unless the FDA has taken definitive action with respect to a device. This means that FDA has thoroughly considered an issue and promulgated a requirement that is both a ceiling and a floor, as is the case with performance standards for Class II devices. There should be no preemption where FDA has merely imposed minimum requirements. For example, recent court decisions have found preemption because the FDA has granted premarket approval to a device. Premarket approval is just a floor, it does not guarantee the ultimate safety of the device. The current breast implant controversy is a clear example of the fact that devices once considered safe can become unsafe as more is learned about them. In the absence of a definitive federal guarantee of safety, there should be no preemption of state law measures that enhance the safety of a device.

Second, there should be no preemption of state tort laws and other victim compensation measures. FDA action always involves a balancing of risk vs. benefit. A device that may well be dangerous to a small number of people may be approved if the benefits outweigh the risks. Recent court decisions have found complete preemption of tort remedies in the device area. This is particularly unfair in light of the fact that at the time of approval, it is expected that some devices will have harmful side effects. If a device injures a person, and the manufacturer of the device has violated a state law that would compensate that person for the injury, then an

FDA determination that the device may be sold even though it has some harmful side effects should not bar that person from just compensation.

Respectfully submitted,

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STATEMENT BY

RONALD M. JOHNSON, DIRECTOR

OFFICE OF COMPLIANCE AND SURVEILLANCE
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FOOD AND DRUG ADMINISTRATION
PUBLIC HEALTH SERVICE
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES AND ENERGY
COMMITTEE ON SMALL BUSINESS

AND

SUBCOMMITTEE ON HEALTH AND LONG-TERM
SELECT COMMITTEE ON AGING

U.S. HOUSE OF REPRESENTATIVES

APRIL 9, 1992

FOR RELEASE ONLY UPON DELIVERY

Mr. Chairman and Members of the Subcommittees, I am Ronald M. Johnson, Director of the Office of Compliance and Surveillance in the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA). Accompanying me are Gerald Vince, Director of the Office of Regional Operations, and Heinz Wilms, Director of the Division of Federal-State Relations, both in FDA's Office of Regulatory Affairs. We welcome this opportunity to discuss FDA's current activities directed at protecting the American consumer from the threat posed by the promotion and sale of quack medical devices. As you know, the practice of health fraud hurts not only the economic strength of its victims; it also threatens their health and very existence.

The promotion of false or unproven products and therapies for profit is as old as recorded history. It thrives today using pseudo-science to prey on the fears of those desperate for relief. The unproven theories espoused are promoted in ways that seem plausible and convincing even to the most sophisticated consumer.

In regulating these products, FDA assesses the hazards posed by quack devices and fraudulent therapies based upon the risk associated with them. We direct our highest priority to those fraudulent devices that present a direct and immediate hazard to the consumer.

Products that present indirect health hazards can be equally dangerous. Even though they may not pose an immediate danger, they may be substituted for, or delay, proven medical therapies resulting in the progression of the disease's morbidity. The promotion of worthless devices for the diagnosis and treatment of serious diseases like cancer and AIDS by the Paradise Pain Clinic in Las Vegas, Nevada and the Century Clinic in Reno, Nevada are recent examples of this type of health hazard. FDA is committed to stopping these illegal activities within our available resources.

Some fraudulent products do not present a health threat to users but they are painful economically. They are promoted as "quick fix" gimmicks for weight problems, hair loss, aging or other problems consumers believe might be remedied by a "miracle cure." Opaque plastic spectacles that have a series of holes punched through the lens area are an example. Promoters make unsubstantiated claims for their use in vision correction. We have initiated legal proceedings against this type of product. Our Cincinnati District Office recently witnessed the destruction of 2000 pairs of such eyeglasses.

Cancer, arthritis and other often incurable maladies have provided fertile ground over the years for health fraud purveyors. Today, the AIDS epidemic has provided a new market which has been exploited by the promoter using the same techniques and capitalizing on the same vulnerabilities that have been the trademark of the health fraud industry. We have no accurate assessment of the size of the health fraud industry, but we do know it is alive and thriving. Regardless of its size, we have no tolerance for unsafe devices and are committed to using the authorities we have to remove those products from the marketplace.

Stopping the promotion and sale of quack and fraudulent devices is not easy. These purveyors work hard to skirt around the law. We cannot expect to prevent them from trying to market a quack product any more than the local traffic officer, with a radar device in hand, can stop someone from speeding. However, once these purveyors promote or distribute their products, they have crossed a legal line that permits us to step forward with our legal sanctions.

Our ability to halt some health frauds is based on our authority to conduct inspections, collect samples and look at records showing interstate movement in establishments where health fraud products are manufactured or held. This includes clinics in which such products are used. The Food, Drug, and Cosmetic Act prohibits the movement of adulterated and misbranded products. Health fraud products may be adulterated or misbranded in several ways, such as their failure to perform safely or effectively, failure to have clearance through FDA, or their false claims and misrepresentations. Our available remedies to correct the problem include seizure, injunction, criminal prosecution, import detention, administrative detention, banning and now, with the passage of the Safe Medical Devices Act of 1990, civil penalties and mandatory recalls. Also, if a device, fraudulent or otherwise, is marketed without premarket notification, FDA can take action against it or the manufacturer.

Even with these legal remedies, however, we believe our most effective protection against these fraudulent products is consumer awareness. Publications from FDA and elsewhere, medical reports about health fraud and public forums, such as this hearing, are vital. Consumers need to protect themselves by being well-informed. They need to know when they may be looking at quackery, or when the purveyor of health fraud is looking at them with a compassionate pitch but deceitful eye.

If consumers confronted with a product or treatment can answer "yes" to the any of the following questions, then they should be aware of a likely fraud:

> Does the product promise a quick and easy cure or change?
> Is the product promoted for treating a wide variety of ailments?
> Is the product a "secret remedy" not available anywhere else?
> Is the product promoted by using testimonials from ex-patients?

Is the product available only from the firm by mail order with advance payment?

Legally recognized practitioners may practice their healing art without interference from FDA. However, they may not treat patients with devices that have no proof of effectiveness and pose a safety hazard.

In an effort to target effectively, and coordinate our activities aimed at health fraud, FDA, through our Federal-State Relations Division, works with other FDA components to: facilitate public information and education campaigns; facilitate communication between public health professionals and regulatory officials; provide a central point for FDA health fraud information; and coordinate our work and information with other federal, state and local governments.

We are encouraged about our new working relationships with the National Association of Attorneys General (NAAG) and the Association of Food and Drug Officials (AFDO). Since the first of this year our Federal-State Relations Division has hosted a biweekly conference call with these two organizations to target health fraud abuses calling for regulatory attention. We appreciate the participation of professionals from such states as Arizona, California, Iowa, Minnesota, Missouri, New Mexico, New York, North Carolina and Texas. Although this program is relatively new, we have every reason to believe it will be effective.

Our recent meeting in Washington, D.C., with the Association of Food and Drug Officials was positive. We anticipate holding future meetings of this type. Through this program, we are encouraging the participation of other states' officials that may be interested in our activity.

At the federal level, we assist other agencies, such as the Federal Trade Commission (FTC), in their effort to control fraud. For example, we recently provided the FTC with expert medical advice to support the agency's claim against the unsubstantiated promotion of the Viralizer System as a cold remedy device. The mass media promotion of this device induced unwary consumers to part with their money by representing that the product was approved by FDA. Consumers should be wary of any device or product that is advertised as FDA-approved, because it is unlawful to make such a claim.

To further combat medical fraud, FDA has established a toll-free telephone line for health professionals so they can have direct access to the Agency's Office of Health Affairs. Callers may ask our medical staff about questionable promotional activities and practices or alert us to health care products that may require FDA regulatory attention. The service is available during normal business hours at 1-800-238-7332 or 1-800 AD-US-FDA.

A year ago our National Health Fraud Task Force launched a program to monitor suspected fraudulent AIDS products and therapies in the states most affected by the AIDS epidemic. A major emphasis is placed on providing support for existing State AIDS Tasks Forces. To date, six such groups have been established in Michigan, Colorado, Texas, Georgia, Louisiana and California.

We have increased our attention to efforts to unearth fraudulent products and remove them from the market. So far this calendar year, in addition to assisting the FTC on the Viralizer System, we issued or approved Warning Letters involving four different fraudulent devices, including two biofeedback devices, an energy frequency generator and a test kit for body pH and parasites. These products made claims for a number of diseases. We have assisted the States of Utah and Wisconsin in support of their actions against a fraudulent electronic diagnostic machine. We have also recently filed a multi-count indictment in California against promoters of a variety of health fraud products.

We are still implementing the new authorities provided to us with the passage of the Safe Medical Devices Act of 1990. Our personnel are receiving additional training in investigative interviewing techniques and many have added skills through training at the federal law enforcement facility in Glenco, Georgia. We have begun to staff our Office of Criminal Investigations, and we look forward to working with these highly qualified investigators. We are confident that our activities directed toward reducing consumer exposure to fraudulent medical products and medical quackery will enhance our consumer safety mission.

This concludes my statement. My colleagues and I would be pleased to respond to any questions you may have.

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TO: RON WYDEN, CHAIRMAN, COMMITTEE ON SMALL BUSINESS, SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES AND ENERGY

EDWARD ROYBAL, CHAIRMAN, SELECT COMMITTEE ON AGING, SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE

FROM: GRAYDON FORRER, SUBCOMMITTEE ON REGULATION COUNSEL, AND SUBCOMMITTEE STAFF

SUBJECT: RECENT TRENDS IN MEDICAL DEVICE QUACKERY; AGED ARE EASY MARKS FOR GROWING TRIBE OF CHARLATANS AND RIP-OFF ARTISTS

April 3, 1992

At your direction, the subcommittee staffs have begun a joint investigation into recent trends in medical fraud and quackery targeted at the elderly.

> According to health policy experts and recent news reports, health fraud now costs American consumers and insurers up to $80 billion a year. These frauds are perpetrated in every part of the country and cover every part of the industry -- from large-scale insurance frauds to kick-backs on unnecessary drug and device sales to bounty hunter payments for steering patients to hospitals and rehab clinics. Healthcare fraud is, in short, a booming industry that seems to evade concerted efforts to control. As Edward Kuriansky, a New York Special Medicaid Fraud Prosecutor told *U.S. News and World Report* in a recent article on Healthcare fraud: "for every loophole we close, the voracious provider seems to find another."
>
> Healthcare fraud perpetrators often target the elderly because of their chronic need for medical attention. This is especially true of quack and dubious providers who see the elderly as easy marks for their "miracle" cure promises.

> This subgroup of healthcare fraud, represented by both organized racketeers and independent charlatans, may now account for over $10 billion of the health-related, consumer rip-offs. There is every indication that the problem continues to grow.

On Thursday, April 9, the subcommittees will hold the first of several hearings examining various aspects of medical quackery in America. These hearings will focus on whether state and federal consumer protection agencies adequately protect our elderly citizens from false, deceptive and misleading curative claims made on behalf of medical device manufacturers and practitioners, some of whom promote the use of a wide variety of unproven and untested medical device products with little or no accountability to regulatory authorities.

The subcommittees will identify and review current developments in medical device quackery and the enforcement loopholes that enable both medical device manufacturers and practitioners to escape the full force of state, local and federal consumer protection laws.

Specifically, the subcommittees will hear testimony regarding:

-- **Patient deaths resulting from unproven and untested medical treatments, including the use of unsafe medical devices in "Quack" medical clinics for diseases such as cancer, arthritis and AIDS.**

-- **"Quack" clinics charging thousands of dollars for highly questionable and unnecessary medical diagnoses and treatments, or who may use dubious medical devices.**

-- **Loopholes in federal laws that enable medical quacks to flourish in an atmosphere of inconsistent enforcement.**

-- **The lack of coordination among federal and state regulatory agencies in their efforts to crack down on untested and unproven medical devices.**

-- **The difficulties faced by State Attorney General Offices left to prosecute quack practitioners under state consumer protection laws which are unable to reach interstate scams.**

MEDICAL QUACKERY: A BRIEF OVERVIEW

Medical quackery of all kinds has long been the bane to consumers. Senior citizens, desperate to be restored to good health and alleviate a myriad of problems associated with aging, are particularly susceptible to the unproven and untested claims of medical charlatans. Further, dubious practitioners and medical snake-oil sellers are quick to turn skepticism about the efficacy of traditional medicinal treatments for chronic illnesses to their advantage with the promise of a miracle cure.

In isolation, many of the unproven or useless practices, devices and products promoted to the elderly as panaceas for disease and illness may be relatively harmless and cost individual consumers merely a few dollars. In some instances, alternative medicine may actually prove useful in the treatment of a wide number of conditions. However, far too many products, procedures and devices pose a serious health risk when consumers avoid standard medical treatment in favor of the medical miracle.

Further, the impact cost to the U.S. healthcare system as a result of these frauds is staggering.

> The Pepper Report on Medical Quackery, prepared in 1984 by the Subcommittee on Health and Long-term Care by then Chairman, Claude Pepper, called medical quackery a "$10 billion dollar scandal." However, several leading medical quackery experts told the subcommittees that the dollar amount today far exceeds this figure.

No comparable figures regarding the current, up-to-date cost of medical quackery to the healthcare system are available. No Federal agency maintains systematic oversight of the field of medical quackery and its impact cost to the U.S. healthcare system.

Increased federal efforts to reduce and curtail medical quackery must be undertaken to effectively guarantee the health safety of our elderly citizens. These efforts must actively combat potentially dangerous, untested and unproven medical remedies, procedures and devices.

CURRENT TRENDS IN DUBIOUS MEDICAL DEVICES

Recent news reports in the Wall Street Journal ("Amid Lax Regulation, Medical Devices Flood a vulnerable Market," 3/24/92, page 1A) and the New York Times ("F.D.A. Faulted on Inspection of Medical Devices," 3/26/92, page A17), as well as hearings held by the House Energy and Commerce Subcommittee on Oversight and Investigations, highlight the difficulties that the U.S. Food and Drug Administration (FDA) faces in enforcing the current FDA law on medical devices. However, because this law was developed for the traditional healthcare market, recent federal enforcement efforts have overlooked the realm of dubious medical devices, how they are manufactured and how they are used. Many manufacturers of dubious medical devices make every effort to skirt the traditional health care market and in virtually every instance, seek to avoid the close scrutiny of the F.D.A.'s Center for Devices and Radiological Health (CDRH).

Oftentimes, the medical charlatan operates with much confidence because, as pointed out in the 1984 Pepper Report, there is no specific authority in the Food, Drug and Cosmetics Act (FDCA) to address quackery or health fraud problems. The key to federal enforcement lies in whether a product or device is "misbranded," and, as described in Section 502 of the FDCA. In essence, federal law becomes active if and only if the label or the claims made on behalf of a device are in any way false or misleading.

However, snake oil promoters and practitioners can easily skirt FDCA strictures by simply failing to (1) register with the FDA, (2) list products that make therapeutic claims, and, (3) provide the FDA with information required under Section 510 of the FDCA.

In addition, quack medical device manufacturers are typically able to avoid the dictates of federal device law and the medical device approval process through the use of broad and overt disclaimer labeling. This labeling may read as follows:

PLEASE NOTE
NO MEDICAL CLAIMS ARE MADE OR IMPLIED IN THE
USE OF THESE DEVICES. FEDERAL LAW PROHIBITS THE USE OF
THIS TYPE OF EQUIPMENT FOR THE TREATMENT OF DISEASE

While such a disclaimer is useful in avoiding full FDA regulation of a device, it is also, in many instances, nothing less than a "nod and wink" in the direction of federal medical device regulators.

Manufacturers of questionable medical devices carefully refrain from overt claims. Often, if a specific claim is made on behalf of a device -- for example: "this machine will cure your cancer" -- it is done orally and in the privacy of a medical office or at the point of sale. Consequently, such claims are exceedingly difficult to prove in court under either the Federal Food and Drug law or under state consumer protection or healthcare fraud laws.

Manufacturers and practitioners have come to rely on the "experimental" nature of a device as sufficient to keep federal regulators at bay. Because these devices are frequently described as "experimental" or as diagnostic tools, the burden of failure can easily be shifted away from the individual device or practitioner. For example, if a cancer patient treated with one of these devices were to die, the manufacturer or practitioner could easily claim that the patient (1) succumbed to the disease, (2) failed to follow the recommended course of treatment, or, (3) became a victim of traditional medicine. In addition, many practitioners and manufacturers can always fall back on the excuse that the device is only experimental and therefore, like traditional medicine, can not be expected to be 100% percent guaranteed.

Often, device manufacturers and practitioners rely on word-of-mouth and endless stacks of personal testimonials to substantiate the usefulness and curative value of their machines. Unlike complicated tests and lengthy research, the testimonial has the advantage of being personal and un-verifiable. Research can be called into question, but a letter from an elderly cancer victim attesting to the value of a treatment or device is subjective and unassailable.

WEAK FEDERAL ENFORCEMENT SHIFTS RESPONSIBILITY TO STATES

Federal agency impotence to come to grips with the wide range of device and quackery practice shifts enforcement responsibility to the states and their consumer protection laws. However, states also face great difficulty in attacking these scams for the following reasons:

(1) State enforcement agencies are inadequately funded.

(2) States lack the appropriate expertise to fully assess the safety and efficacy of a device.

(3) Consumers, out of loyalty to the quack practitioner or personal embarrassment, often do not report problems associated with the use of phoney medical devices.

Nevertheless, several states are making a concerted effort to eliminate dubious devices from the market, and to prosecute quacks under their individual state consumer protection or professional practice laws. But state enforcement efforts are often haphazard. There are fifty state laws, and fifty consumer protection agencies and professional licensing boards, attempting to combat this problem. Inter-state cooperation is slight and prosecutorial resources are limited. As a result, state ability to pursue a manufacturer or practitioner can end at the border.

States lack technological expertise to evaluate devices, and are forced to rely on FDA assistance to make a credible case against quacks. These cases are difficult to explain to judges and juries, and all too often, the only penalty available to a state is a misdemeanor conviction.

Several State Attorneys General have told the subcommittees of effective work and useful cooperation with FDA Regional Offices in prosecuting spurious device manufacturers and practitioners. However, FDA efforts appear to break down once cases are referred to Washington for approval.

> One state criminal investigator told the subcommittee regarding FDA prosecutions: "you really have to get on them" to make a case.

All too often, by the time the FDA acts the harm is done and the practitioners and the fraudulent machines are long-gone.

THE APRIL 9 HEARING

The April 9 hearing will look at several cases that exemplify particular problems with questionable medical devices.

First, the subcommittees will hear testimony on several cases where states have had to act in lieu of federal action. These cases include:

(1) Idaho: A criminal prosecution against a dubious medical device manufacturer and practitioner. The state prosecuted and won a grand theft conviction involving a patient who died of cancer after being "cured" by a practitioner using a questionable medical device. The Idaho Attorney General Office will describe help received from FDA's regional offices. They expected a federal case to be made against the device manufacturer, only to see the case die in the Washington, D.C. bureaucracy.

(2) Nevada: A Las Vegas Clinic promotes a device to treat "pain" and which allegedly "cures" cancer, "Lyme" disease, arthritis and AIDs. An Oregon paraplegic was promised that "he would be walking within a month." He is still in a wheel chair, after forking out more than $5,000 dollars to the quack practitioner.

One Idaho woman told the subcommittees that, at this same clinic, her mother was "treated" for cancer and eventually died after relying exclusively on the clinic's treatment program. The clinic owner has no medical credentials and no documentation regarding the effectiveness of his "experimental" machine (other than personal testimonials).

In addition, the subcommittees will hear testimony from an undercover reporter documenting how one Nevada based clinic uses a untested and unproven "diagnostic" device to identify and treat non-existent diseases. The clinic then charges thousands of dollars for further questionable treatments to "cure" these non-existent conditions.

The subcommittees will also hear from representative of state Attorney's General offices concerning problems in coordinating federal and state efforts to combat quackery. And, finally, a nationally recognized medical fraud and quackery expert will demonstrate a wide variety of questionable practices and devices currently marketed to consumers.

Activator Methods, INC.
DR. ARLAN W. FUHR, PRESIDENT AND CO-FOUNDER

June 3, 1992

Roy Wyden, Chairman
Subcommittee on Regulation, Business
Opportunities & Energy
Small Business Committee
U.S. House of Representatives
Washington, D.C. 20515

Dear Congressman Wyden:

I was dismayed to find the Activator instrument (AI) mentioned as an example of "dubious" and quack devices in testimony of John Renner, M.D., before the U.S. House of Representatives, Subcommittee on Aging and Small Business on April 9 (Renner, 1992). Dr. Renner has provided erroneous information to the Congress, in that he describes the AI as a "gadget used by chiropractors to show where the spine or pelvis or temporomandibular joint (TMJ) is out of place." This statement, made by the president of the Consumer Health Fraud Information Research Institute (CHIRI), is false; I can only assume that Dr. Renner either has not taken the time to learn anything about the AI, or is unconcerned about the veracity of his claims.

The AI is a hand-held mechanical device It is registered with the Food & Drug Administration (A 375768), and delivers a controlled and repeatable force. The instrument is not an assessment device, and does not indicate "where the spine or pelvis or TMJ is out of place" (Renner, 1992). It is this sort of fundamental misunderstanding that suggests a very cursory familiarity (if any) with the AI on the part of CHIRI president Renner.

The AI is widely employed by chiropractors as a treatment device and has been in use for 20 years. The instrument produces a maximum of 0.3 joules of potential energy; the force actually delivered to the body surface overlying a joint varies as a function of the preload force (exerted by the clinician's hand), the direction of force and the excursion of the instrument's stylus (which can be regulated by the operator). Preliminary studies (Fuhr & Smith, 1986; Smith et al., 1989) have suggested that, in animal subjects, the AI can produce 1.3 mm of relative bone movement, 0.5 degrees of vertebral rotation and 1 mm of translation. The thrust of the AI is similar to that which is derived by hand by most chiropractors, although the audible "popping" that often accompanies more forceful manual manipulations is much less common with the AI.

On the basis of the available data, AI adjusting received a rating of "promising to established" when reviewed by a panel of clinicians, scientists and educators within the profession (Mercy Center Conference, 1992); the guidelines offered by this panel have been endorsed by the Federation of Chiropractic Licensing Boards and by the American Chiropractic Association. Instruction in the use of the AI is provided by at least 8 of the 15 chiropractic colleges accredited by the Council on Chiropractic Education (a voluntary educational accrediting agency recognized by the U.S. Department of Education). Contrary to Dr. Renner's assertion, and to the best of my knowledge, reimbursement by workers' compensation insurance plans for chiropractic care involving the AI is available *everywhere* throughout the United States.

We (Activator Methods, Inc.) have taken pains in recent years to insure that our promotional literature avoids any hint of unsubstantiated claim for the AI and related methods. We have attempted to provide serious, scholarly self-criticism (e.g., Osterbauer & Fuhr, 1990), and are active within the research community in efforts to raise consciousness about the scientific status of this and other methods of healing. Accordingly, Dr. Renner's criticism is not only factually incorrect (in that he mistakes the AI for an assessment procedure), but is also ethically unjustified. Given that I share many of Dr. Renner's concerns about the extent of health fraud, quackery and health care misinformation, it is ironic that he chooses to disseminate misinformation about the device we offer. I have in the past invited Dr. Renner to contact my office to learn more about the AI, its use, and the state of the literature concerning the device, and I extend to you the same invitation. I have never had a response from Dr. Renner, but I look forward to hearing from you so that the record on this matter can be corrected.

Thank you for your attention to this matter.

Sincerely,

Arlan W. Fuhr, D.C.
President

CC: Richard Miller, A.C.A. Governmental Relations

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The Foundation for Homeopathic Education and Research

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April 22, 1992

Rep. Ron Wyden
U.S. Congress
Washington, D.C. 20515

Dear Honorable Representative Wyden,

I am a public health educator trained at the University of California at Berkeley who, like yourself, is concerned about health fraud and about safe and effective health care. Out of this concern I have developed a serious interest in homeopathic and natural medicine.

Although there are various individual instances when health fraud takes place and where increased regulation is certainly essential, the vast majority of health and medical professionals who use homeopathic and natural medicines are providing safe and often effective health care.

Dr. John Renner and Randall Everitt has suggested that practitioners of natural medicine prey upon the poor, the elderly, and the infirmed. However, they cite no surveys to support this, nor do they seek to find if the people who seek natural health care feel benefit from it.

Actually, according to surveys published in the **New England Journal of Medicine** (see enclosed), people interested in natural medicine tend to be more educated than individuals who don't. This suggests that people who are pursuing natural health care are not simply desparately or illogically seeking help, but that these people are making rational and intelligent decisions on how to help themselves and their families.

I have seriously studied homeopathic medicine, not to be a practitioner but to be an educator. Enclosed is an article from the **British Medical Journal** which reviews 107 controlled clinical trials, 81 of which showed that homeopathic medicines were effective in treating a host of conditions.

All four of the books that I have authored contain forewords and/or supportive quotes from esteemed physicians, professors, and world leaders, including the Physician to Her Majesty Queen Elizabeth II, the former Assistant Secretary General of the United Nations, and professors at Harvard and Yale School of Medicine. Dr. Renner and anyone who suggests that these people are being hoodwinked by fraudulent practitioners is simply ill-informed and seriously deluded. You must question the testimony of such individuals.

Enclosed also is a review of the status of homeopathic medicine in the world. Homeopathy is so popular in parts of Europe and Asia that it is inappropriate to consider it part of "alternative medicine." Rather, homeopathy is an integral part of mainstream medicine.
--32% of French family physicians use homeopathic medicines.
--20% of German physician use homeopathic medicines.
--45% of Dutch physicians consider homeopathic medicines to be effective.
--42% of British physicians refer patients to homeopathic physicians.
--there are 120 five-year homeopathic medical colleges in India, and there are drug de-tox clinics in six police stations in New Delhi in which homeopathic medicines are the primary therapy uses to treat drug addicts.

Homeopathic and natural medicine does not necessarily replace conventional medicine, but offers an important complement.

I ask that you to submit this testimony into the official record of your proceedings on quackery. If I can be of further assistance to you and provide you additional supportive material on homeopathic medicine, please do not hesitate to let me know if you would like further testimony.

Sincerely,

Dana Ullman, M.P.H.

cc: Rep. Edward Roybal

New England Journal of Medicine
Jan 2, 1992

of course expect it to be as polished as the discus- ns in our Case Records or review articles.

We intend to select patients and problems similar to se that clinicians might be expected to encounter in course of a busy practice. We will choose interest- g perplexing problems — frequently those in which doctor can make a difference to the patient. We ll not shrink from rare disorders if they teach an portant lesson, but we will not serve up a steady et of epinephrine-secreting pheochromocytomas, bry's disease, porphyria, atrial myxomas, or eosino- ilic granulomas.

Solving the diagnostic problems that confront us om day to day, identifying what is and what is not portant for a patient, and making the complex ade-offs between the benefits and risks of tests and eatments are paramount functions of the physician. Machines have not replaced us yet. But the cognitive kills these tasks require are rarely explicated. In- tead, students and house officers are expected to de- elop these inchoate abilities by the "watch one, do ne" approach. By carefully selecting specific exam- les of clinical reasoning, we hope to demonstrate oth superb and imperfect problem-solving. These ex- mples will not only instruct but also illustrate why, despite all the newly imposed annoyances, we still take considerable satisfaction in caring for the sick.

JEROME P. KASSIRER, M.D.

SOUNDING BOARD

PHYSICIANS AND HEALERS — UNWITTING PARTNERS IN HEALTH CARE

ALTERNATIVE medicine has long played an important part in the care of people with health problems in this country. Although there has been no comprehensive assessment of its use, there are good reasons to believe that alternative medicine has many adherents among all social classes. Most physicians are unaware of its popularity, much less that many of their own patients are also being cared for by practitioners of alternative medicine.

A MUDDLE OF NAMES, BELIEFS, AND PRACTICES

There is no widely accepted term for the practices grouped under the rubric of alternative medicine. "Holistic medicine" (or "wholistic medicine") is a popular term, but it is so vague as to be nearly meaningless. The practices are also commonly described by other terms that are often ambiguous, such as unorthodox, complementary, unconventional, natural, traditional (or nontraditional), contemporary, and New Age. "Alternative medicine" seems to be the most widely used term and one that is reasonably unambiguous. It can be defined to refer to a heterogeneous set of practices that are offered as an alternative to conventional medicine for the preservation of health and the diagnosis and treatment of health-related problems; its practitioners are often called healers.

These alternative practices represent a hodgepodge of beliefs and treatments. Many are well known, others are exotic or mysterious, and some are dangerous. They are based on no common or consistent ideology, theory of illness, or treatment. They derive from a wide variety of sources: ethnic and folk traditions, mainstream medical practices, established religions or semireligious cults, philosophies or metaphysical movements, and health-and-wellness groups exploiting the growing rebellion against technology and the perceived impersonalization of medical care. Their leaders and practitioners reflect this diversity. Most are sincere and committed, sometimes well educated, and often charismatic, but some are charlatans. There is very little information available about their education, training, beliefs, or practices. Although chiropractors are licensed in every state and acupuncturists are registered under the acts regulating medical practice in several states, most other practitioners of alternative medicine are unlicensed, unregistered, and unregulated. They are rarely challenged as practicing medicine without a license and are very rarely sued for injury or negligence. It is notable that some physicians and nurses use methods derived from alternative medicine in addition to conventional medical treatments.

Although there is no recognized system of classification for alternative medicine, its practitioners can be conveniently divided into four categories, based on the type of treatment they use. The spiritual and psychological category includes faith healers from established religions, psychics and mystics who engage in paranormal healings and various divinations, and those using psychological techniques such as mental imaging, hypnosis, and laughter therapy. The nutritional category includes those who recommend herbal, vitamin, and mineral dietary supplements and prescribe specific diets, such as the macrobiotic diet. The drug and biologic category comprises specialists in the use of assorted chemicals, drugs, serums, and vaccines — e.g., treatments to enhance the immune system, homeopathy, and the injection of live cells from fetuses and animals. The fourth category, involving treatment with physical forces and devices, includes chiropractors, massage and touch therapists, acupuncturists, and practitioners of various electrotherapies. Other methods are difficult or impossible to categorize, such as aroma therapy and iridology, the diagnosing of internal diseases by examining the iris of the eye.

THE WIDESPREAD USE OF ALTERNATIVE MEDICINE

The use of alternative medicine varies greatly in frequency in different parts of the world and various sections of the United States, depending on historical circumstances, ethnic and folk traditions, the degree of cultural isolation, the personalities of local leaders, and the degree of support or suppression by local governments.

Unconventional medical practices have long been popular in the United States, but were especially so in the latter part of the 19th century and during the 1920s. There is mounting evidence of a resurgence of interest today. McGuire recently carried out an extensive assessment of healing groups in a middle-class suburb in northern New Jersey.[1] She identified and studied in detail 31 different social groups that used at least 1 of 73 different alternative practices related to health. Contrary to what is commonly believed, the participants in these healing practices were well educated (all were high-school graduates, 56 percent had bachelor's degrees, and several had advanced degrees) and well off (their annual family income in 1982 averaged $30,000). Ninety-five percent were white, and all the major religions were represented. Virtually all the group members used medical treatments along with nonmedical healing. Cassileth et al. surveyed 660 patients with cancer; 304 were receiving health care from physicians, and 356 from alternative practitioners.[2] Eight percent of those receiving alternative care had never had any conventional treatment, and 54 percent of those receiving conventional treatment also sought alternative medical care; 40 percent of these patients abandoned conventional care after they adopted alternative methods. Over half the practitioners providing unorthodox remedies were physicians. A survey of six primary care clinics in rural West Virginia showed that in the course of a year 73 percent of the patients used folk remedies to treat major or minor conditions.[3]

Recently, the Energy and Commerce Committee of the House of Representatives asked the Office of Technology Assessment to investigate alternative cancer treatments and develop guidelines with which to evaluate their medical value. After a three-year study, the final report was published in September 1990; with 234 pages and 993 references, it is a very thorough and apparently objective assessment.[4] The investigators estimated that thousands of patients with cancer use alternative therapies, and thousands more seek to do so. They also presented several ways to obtain more information about nonconventional treatments and make it available to patients with cancer. The authors of the report concluded that better studies of the efficacy and safety of the various alternative methods were needed.

The best assessment of the prevalence of alternative medicine comes from Great Britain. Fulder and Munro's survey conducted in the United Kingdom in 1980-1981 showed that there were approximately 13 million visits to practitioners of alternative medicine yearly, these authors estimated that there were 7500 such practitioners in the United Kingdom — 30 percent of the number of general practitioners.[5] The comprehensive report of the British Medical Association in 1986 identified 116 alternative medical treatments that were used reasonably often in Great Britain.[6] In 1988 the Royal Society of Medicine reported on a colloquium it sponsored that brought together physicians prominent in conventional medicine, representatives of several alternative medical groups, and government health officials for an amicable and collegial series of meetings.[7] The report concluded that more and better studies were needed of the efficacy of the various types of alternative practices; it recommended further "bridge building" between conventional and alternative medicine.

The use of alternative medicine has increased greatly in France as well in recent years, causing the French government to establish a foundation to study "soft medicine" and a working party to conduct clinical trials of homeopathy.[8] Five French universities now offer certificates in various areas of alternative medicine. In 1981 the Ministry of Health and Environmental Protection of the Netherlands published a report by its Commission for Alternative Systems of Medicine in response to increasing public demand for legal access to alternative medical care.[9] The commission reported that 7 percent of the Dutch population visited a practitioner of alternative medicine every year and that 18 percent acknowledged visiting such a practitioner at least once. There have also been recent reports of the growing use of alternative medicine in Australia[10] and New Zealand.[11]

ADVANTAGES AND DISADVANTAGES

There are many reasons that people choose alternative medicine in addition to conventional medical care, or instead of it. Some reject conventional treatment because of disappointment with the outcome of a past encounter or with the care provided for a present condition, especially when a hopeless prognosis has been reported or when the patient, a family member, or a friend has had unpleasant or painful side effects of treatment. For others the reason is that care has been impersonal, costly, inconvenient, unavailable, or inaccessible. Many people think that conventional medicine is unsuited to certain conditions; that physicians do not understand, are incompetent to treat, or are uninterested in certain health problems; or that conventional medicine is too complex and technologically oriented. Some immigrants and culturally isolated groups in rural and inner-city areas continue to use the traditional practices of folk medicine with which they have become comfortable. Alternative medicine is attractive to many because of the influence of role models and decision makers, such as religious authorities, family members and friends, celebrities, and representatives of the media. Others are drawn to the contemporary health-and-nature movement and its recommendations to "treat the whole person" and "take charge of your own health," as well as to its promise of greater freedom of choice and to attractive leaders who frequently provide patients with acceptable, readily understandable explanations of disease.

There are some real and some potential advantages to alternative care. Most of the remedies it provides are harmless and inexpensive, and they are generally used to treat benign and self-limited diseases. By using them, patients avoid conventional treatments that may be uncomfortable and may sometimes be costly, harmful, or both. Alternative medicine often renews hope in patients with a fatal disease or a serious chronic illness that does not respond to conventional care; many such patients feel that their physicians are no longer interested in them. Occasionally the pharmacopeias of healers turn out to be helpful, and some unorthodox remedies have indeed been found to be effective in controlled clinical trials.[12-14] Two recent independent, randomized studies evaluated unconventional adjuvant treatments for cancer (one used hydrazine sulfate, the other psychological intervention); both studies seemed well done methodologically and were published in peer-reviewed journals. The authors concluded that the interventions were associated with increased longevity and that there was improvement with regard to some subjective factors.[15,16] However, Cassileth et al. found no significant improvement in longevity among patients with advanced cancer who received an "immune-enhancing" alternative treatment along with a conventional one, as compared with patients who received only conventional treatment; moreover, the quality-of-life scores were higher in the latter group.[17] Shekelle et al. summarized the medical literature on spinal manipulation for low-back pain, including 22 controlled trials, and reported on a comprehensive study of the circumstances in which this treatment is appropriate.[18] Many of these studies found substantial benefit, but most were inconclusive. The degree of agreement among the physicians and chiropractors evaluating the studies was poor.

Alternative care has several important disadvantages and some potential dangers. It may be indirectly hazardous if it delays the provision of conventional care for serious illnesses that could be treated more effectively by that method. Some alternative therapies are directly toxic or cause harm as a result of a contaminant or improper use of a remedy. Alternative medicine is by no means always inexpensive, and it may often be more costly than conventional care. Some treatments are fraudulent; a congressional study in 1984 estimated the annual cost associated with health-related fraud in the United States at more than $10 billion.[19] Success with alternative care in the treatment of one illness may motivate patients to use similar treatments later for more serious conditions that could be treated more successfully by conventional means.

DEALING WITH PATIENTS WHO USE ALTERNATIVE MEDICINE

Most physicians in this country are unaware of the widespread use of alternative medicine and the great diversity of the methods involved. Many believe the use of these techniques is limited to a few of society's marginal groups or to the patients of other doctors. It should be clear from the discussion above that this is not the case. There is strong evidence that patients in every social, economic, and educational class seek and use alternative care. Indeed, in the university cities with which we are acquainted, there are several widely circulated periodicals that describe many alternative treatments favorably and carry advertisements for a variety of healers and for events at which speakers address groups on these subjects. The readership of these periodicals and the audiences at these meetings include university faculty members and students.

How should physicians deal with patients under their care who are also being treated by practitioners of alternative medicine? Frank discussion with a patient about alternative medicine and the particular method being used would seem to be a prudent first step. Unbiased information about alternative medicine is hard to acquire, but the American Medical Association and its state affiliates, medical-specialty societies (e.g., the American Cancer Society), organizations promoting alternative medicine,[20] and self-help groups are useful sources. In some situations, after attempts at education and persuasion have failed, it may be necessary to press the patient to choose between conventional and alternative treatments, especially when it is likely that the alternative therapy will be harmful or when malpractice liability can be predicted to result. In other cases it may be advisable to accept the situation and monitor the outcome — if, for example, the practitioner is treating a minor medical problem with a harmless remedy.

When the medical condition is serious or the details of the alternative treatment are unknown, it may be useful to contact the practitioner directly. If it appears that treatment is safe and will not interfere with conventional medical care, it may be expedient to permit both treatments to be carried out concurrently, with monitoring by the physician. In some situations the practitioner of alternative medicine can be persuaded to help convince the patient that the proposed conventional treatment is better for the patient's problem. One option used by some physicians caring for patients with chronic diseases in advanced stages who are considering alternative medicine is to recommend participation in an experimental treatment program carried out by conventional medical investigators. Finally, it must be kept in mind that some alternative medicial treatments are efficacious and that some established medical treatments (e.g., those using digitalis, opium derivatives, and salicylates) were first used by practitioners of alternative medicine.

Patients choosing between conventional and alternative care are often confused by the conflicting opinions and recommendations offered them. Most physicians belittle alternative medicine as illogical and maintain that its methods are not subjected to scientific scrutiny. For their part, advocates of alternative medicine disdain conventional medicine as narrow and prejudiced, a discipline that uses only a limited number and kind of treatments and measures success only by changes in laboratory values and prolongation of life. Data that permit informed decisions are not available to most patients, who need to know about the kinds of medicine, both conventional and alternative, that are relevant to their particular health problems.

Such information was compiled recently about cancer treatments by the Office of Technology Assessment.[4] But patients also need standards for diagnosis and treatment that they can use in comparing the available options. A useful first step would be to create a panel made up of representatives of conventional and alternative medicine and members of the public and charged with negotiating a consensus on such standards. Reaching the consensus would be difficult. Any agreement would have to be acceptable both to the proponents of controlled clinical trials and to advocates of alternative medicine, the end points of which are often difficult to quantify. But beyond their obvious importance for patients, the standards would be invaluable to legislators, health insurers, the judicial system, and health planners — groups whose support could provide the necessary impetus for consensus. The time is opportune to begin such an endeavor.

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The *Journal* will be adding a full-time Deputy Editor to its in-house staff. Applicants must have an M.D. degree and experience in clinical investigation. Clinical practice in a teaching hospital and editorial experience are desirable. Those interested should write to the Editor-in-Chief (marking the envelope "personal attention"), at 10 Shattuck St., Boston, MA 02115, enclosing a curriculum vitae.

CORRESPONDENCE

HEPATITIS C VIRUS REPLICATION

To the Editor: Farci et al. (July 11 issue)[1] reported longitudinal data on the levels of hepatitis C virus (HCV) RNA in patients with post-transfusion non-A, non-B hepatitis and in experimentally infected chimpanzees. They drew several interesting conclusions about the patterns of HCV infection and the possible clinical value of the polymerase chain reaction (PCR) in classifying potentially infected persons according to those whose infection has resolved, those with persistent infection, and those with active infection. Most of their conclusions are clearly valid, but we are concerned that the effect of the manipulation and storage of the specimens on the stability, and hence the detectability, of HCV RNA may have undermined several observations.

We recently completed a study of the stability of HCV RNA (unpublished data). Using a sensitive PCR assay directed at the HCV genome's highly conservative 5' untranslated region (Cha T-A, et al.: unpublished data), we compared the rate of detection of HCV RNA in donor pilot tube serum subjected to routine screening and supplemental assays (requiring periods of storage at room temperature and several cycles of freezing and thawing) and corresponding fresh-frozen plasma from 27 samples that were reactive to anti-HCV on enzyme immunoassay. We detected HCV RNA in all 16 samples of fresh-frozen plasma that were anti-HCV–positive on supplemental testing (only 2 of which had elevated alanine aminotransferase levels), but in only 10 (62.5 percent) of the serum samples. We also performed controlled, semiquantitative evaluations of

Dear Friends,

This new survey of clinical research on homeopathic medicine verifies homeopathy as a legitimate area of scientific inquiry. The enclosed **British Medical Journal** article reviews a total of 107 controlled clinical studies which were performed between 1966 and 1990, 81 of which indicated positive results. Although many of these studies were flawed in various ways, an analysis of the highest quality studies found that 15 of the 22 showed greater success in patients given a homeopathic medicine than those given a placebo.

For further information about homeopathic research, including laboratory studies, contact:

Foundation for Homeopathic Education and Research
2124 Kittredge St.
Berkeley, CA. 94704

For further general information on homeopathy and for access for books, tapes, and medicines, contact:

Homeopathic Educational Services
2124 Kittredge St.
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Clinical trials of homoeopathy

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Abstract

***Objective*—To establish whether there is evidence of the efficacy of homoeopathy from controlled trials in humans.**

***Design*—Criteria based meta-analysis. Assessment of the methodological quality of 107 controlled trials in 96 published reports found after an extensive search. Trials were scored using a list of predefined criteria of good methodology, and the outcome of the trials was interpreted in relation to their quality.**

***Setting*—Controlled trials published world wide.**

***Main outcome measures*—Results of the trials with the best methodological quality. Trials of classical homoeopathy and several modern varieties were considered separately.**

***Results*—In 14 trials some form of classical homoeopathy was tested and in 58 trials the same single homoeopathic treatment was given to patients with comparable conventional diagnoses. Combinations of several homoeopathic treatments were tested in 26 trials; isopathy was tested in nine trials. Most trials seemed to be of very low quality, but there were many exceptions. The results showed a positive trend regardless of the quality of the trial or the variety of homoeopathy used. Overall, of the 105 trials with interpretable results, 81 trials indicated positive results whereas in 24 trials no positive effects of homoeopathy were found. The results of the review may be complicated by publication bias, especially in such a controversial subject as homoeopathy.**

***Conclusions*—At the moment the evidence of clinical trials is positive but not sufficient to draw definitive conclusions because most trials are of low methodological quality and because of the unknown role of publication bias. This indicates that there is a legitimate case for further evaluation of homoeopathy, but only by means of well performed trials.**

Introduction

A survey of 293 general practitioners in The Netherlands showed that 45% of them think that homoeopathic remedies are efficacious in treating upper respiratory tract infections or hay fever.[1] On the other hand, many doctors do not believe that homoeopathy is an efficacious treatment as it is highly implausible that infinitesimally diluted substances retain their biological effects. It is also often stated that homoeopathy has not been evaluated using modern methods—that is, controlled trials. The first argument may be true, but the second is certainly not true. Reading an article about pollen C30 in hay fever increased our interest in homoeopathy.[2] We could not believe the positive result (was it coincidence?) and therefore we started to search for further reports. Here we present 107 controlled trials of homoeopathy.

Homoeopathic medicine is a system developed by Samuel Hahnemann from the similia concept: "similia similibus curantur." This implies that a diluted, "potentised" agent, which (when undiluted) in healthy individuals induces complaints resembling those of the patient, can be used to cure the patient.

Potentiation is a combination of dilution and shaking of a substance. A plant—for example, *Arnica montana*—is macerated and dissolved in alcohol. One part of this "mother tincture" is mixed with nine parts (D1 potency) or 99 parts (C1 potency) of 90% alcohol (the concentration of the alcoholic solution may vary between manufacturers) and then vigorously shaken. This process can be repeated many times, resulting in very high dilutions (potencies): D6 means one molecule of the original substance in 10^6 molecules of 90% alcohol; C6 means one molecule in 10^{12} molecules. In potencies of D24 or C12 and higher it is very unlikely that even a single molecule of the mother tincture is present. The idea is, however, that higher potencies work more strongly than lower potencies.

Using the similia principle the classical homoeopath tries to find a substance that fits the patient's complaints as much as possible. Unusual symptoms that do not fit the symptom complexes recognised by conventional medicine may be considered even more important than the regular symptoms. This is why homoeopathy is a highly individualised treatment, resulting in different treatments for patients who would receive an identical treatment in conventional medicine. In modern homoeopathy combinations of several or many homoeopathic substances are often used, especially in over the counter preparations. The classical homoeopath will never use this polypharmacy. Also, according to classical homoeopathy a similium must be used and not a potentiation of the causal agent (for example, pollen in hay fever or lead in lead poisoning), which is called isopathy. Phytotherapy is the administration of herbs or low potencies of herbs (D2 or so). These preparations may still have pharmacological effects, and therefore it is sometimes difficult to demarcate phytotherapy from modern homoeopathy, the fundamental difference being the applied low dose toxicology principle in homoeopathy. This description of homoeopathy indicates that it is not just another therapy but a distinct outlook in medicine, and several interpretations have developed, often contradictory to one another.

For this review we searched exhaustively for published reports to investigate the clinical evidence of the efficacy of homoeopathy, regardless of its (to us) implausibility. The positive and negative evidence was weighed against the methodological quality of the research.

Materials and methods

Trials were eligible if parallel index and control groups were included. Crossover designs were also eligible, but controlled studies in animal models were excluded.

Experiments were found by various strategies: a computer search (MEDLINE online 1966-90; keyword homeopathy); checking references extensively, in articles on clinical research and in textbooks[4-5]; checking the proceedings of conferences of homoeopathy; checking the contents of several journals of homoeopathy; personal communication with researchers; writing to and visiting major manufacturers of homoeopathic preparations; and visiting several libraries specialising in homoeopathy. This process of collection took place over a period of more than three years. Trials published in any language were eligible, without restrictions.

Classical homoeopathy uses individual diagnoses and treatments. From a homogeneous group given diagnoses in conventional medicine the patients suitable for homoeopathic treatment can be selected. This results in acceptable participants from both regular and homoeopathic points of view. Individual treatment is prescribed, and then the patients are randomly allocated to homoeopathic or placebo treatment. If necessary, the prescription may be changed in the course of time and, of course, patients who started on placebo stay on placebo.[6]

When the same homoeopathic drug or combination of homoeopathic drugs is given to all patients with a comparable regular diagnosis, trial methodology is the same as in regular medicine. This also goes for trials testing isopathy.

Because the effects of most homoeopathic treatments are meant to last for longer periods, the interpretation of crossover trials is complicated by carryover effects. The analysis will be very difficult, and consequently parallel experiments are preferable.

To explore the possibility that an increasing likelihood of bias (an increasing number of methodological shortcomings) is reflected in the results of the trials, criteria for a methodological assessment of the experiments were established. We put much weight on the number of participants. In most indications for homoeopathic treatment subjective symptoms are the main outcome phenomenon. Substantial improvements of patients in the control group can be expected, and fairly large groups, which are comparable at baseline for prognostic factors, are needed for valid assessment of the efficacy. In trials with limited numbers of participants one cannot be confident that randomisation will equally divide known and unknown confounders over the experimental and control groups. As well, publication bias may be less likely for experiments with large numbers of participants: the effort and costs entailed will increase the likelihood that a paper is submitted for publication. Thus a main argument for our emphasis on relatively large numbers of participants was not the likelihood of type II error, which also depends on the estimated size of the effect, but mainly our worry about incomparability at baseline of the groups and the likelihood of publication bias.

Other major criteria for methodological soundness were randomisation and double blindness. When prognostic factors of the illness, other than the intervention under study, are insufficiently known, random allocation to the contrasted treatments is useful to ensure a comparable prognosis. Double blindness is important for keeping the intervention exactly the same in the contrasted groups except for the homoeopathic treatment, and for an unbiased assessment of the effects. This is especially important if it concerns the relief of subjective symptoms, as is often the case in homoeopathic treatment.

Starting from a maximum score of 100 points, we divided these among seven methodological criteria.

(1) *Patient characteristics adequately described: 10 points*—Description of the syptoms and, if appropriate, of their duration and severity.

(2) *Number of patients analysed: 30 points*—One hundred or more patients per group analysed = 30 points, 50-99 patients per group = 20 points, and 25-49 patients per group = 10 points. A crossover trial with 70 participants (35 given active treatment and 35 given placebo in each period) would score 10 points. In trials assessing the prophylactic effects of homoeopathy the number of patients with the outcome phenomenon was used.

(3) *Randomisation: 20 points*—Twenty points if the method of randomisation was described and correct, 10 points if the method was not described or if some form of pseudorandomisation was applied. If there were fewer than 25 participants per group, half the score was given unless there was prestratification (matching) on relevant items and a table showing comparable baseline characteristics.[7]

(4) *Intervention well described: 5 points*—Adminis-

tration, doses, duration and origin, method of manufacture of homoeopathic preparations.

5, *Double blinding: 20 points*—Twenty points if the placebo was described as indistinguishable, 10 points if double blinding was only mentioned.

(6) *Effect measurement relevant and well described: 10 points*—Measurement of the effect must be sensible and reproducible. Five points each for relevance and adequate description.

(7) *Presentation of the results in such a manner that the analysis can be checked by the reader: 5 points*—Depending on measurement of the effect, at least the mean(s) and standard deviation, standard error, or confidence interval in each group must be mentioned, or the number of patients with a certain outcome (for example, if rates or proportions were used).

Sometimes only part of the score was given if the description was unclear, or if only some of several interventions, measurements of outcome, or data presentations met the criteria. In the second criterion we chose to use the number of patients analysed instead of the number randomised because in many publications drop outs were not accounted for. Often the number of patients admitted was not even mentioned. In the seventh criterion we did not demand confidence intervals for the comparisons between groups because then virtually no trials would score the criterion, with only a few exceptions.

All articles were scored by at least two of us, and differences, which were mainly caused by reading errors or by unclear descriptions in the publications, were resolved by discussions. Most of these differences occurred in patient characteristics and descriptions of measurement of the effect; in these cases the relevance and sensibility had to be judged. The largest difference was 13 points.

Assessment of articles using these criteria provides a score that gives an indication of the methodological quality of each trial. This quality is an important factor in weighing the conclusions of different trials and, of course, on the impact on the reader's opinion of all the evidence presented. We have selected well established methodological criteria,[10] and our assessment can be checked by the reader (table I).

Results

Table I shows some methodological characteristics of the better trials (those scoring 55 points or more). Some good studies have been reported, but overall the methodological quality was disappointing. Patient characteristics were described adequately in 56 trials. More than half of the publications (63) were of trials in which fewer than 25 patients per group were treated. Sixty eight trials were randomised, but only 17 described the method of randomisation. The intervention was adequately or reasonably well described in 80 trials. Seventy five were double blind, but the placebo was described as indistinguishable in only 31 trials. In 67 publications the effect measurement was judged to have been sensible and well described. Sufficient data for the reader to check the analysis were given in 65 trials.

It is difficult to compare the quality of trials that score more or less the same, and in the lower range the results of all studies may be seriously biased because of several methodological shortcomings. Consequently, we present in detail the results of only the best trials (those scoring 60 points or more) (table II).

In 14 experiments some form of classical homoeopathy was tested. Only one of these scored more than 60 points. In a randomised double blind trial Brigo gave one or sometimes two of eight chosen drugs (belladonna, gelsemium, ignatia, cyclamen, lachesis, natrium muriaticum, silicea, or sulphur in a C30 potency) to 30 patients with migraine headache; 30 controls received a placebo. After four months the patients treated with homoeopathy fared much better than the controls on severity of attacks: on a 10 cm visual analogue scale the severity changed from 9·1 to 2·9 in the homoeopathic group and from 8·4 to 7·8 in the control group. Similar differences were found for the frequency and the duration of the attacks.[22]

In about half of the controlled trials (58 studies) the same single homoeopathic treatment was given to a group of patients with comparable conventional diagnoses. Combinations of homoeopathic treatments (polypharmacy) were tested in 26 studies, and isopathy in nine. Only one trial compared dilutions with potencies (a positive trend was found in favour of the potency)[11] and in a few trials different potencies or different homoeopathic substances were compared with each other.

Twenty eight trials were published before 1980, 38 in the period 1980-4 and 41 from 1985 onwards. Forty two trials were published in English, 34 in German, 30 in French, one in Italian, and one in Portuguese. Several trials were published in more than one language (for example, Italian and French); in those cases we chose the reference of the most comprehensive and most easily obtainable publication.

According to conventional diagnoses, several groups

TABLE I—*Scoring of methodological characteristics of clinical trials of homoeopathy*

	Characteristics of patients (max = 10)	Number analysed (max = 30)	Randomisation (max = 20)	Intervention (max = 5)	Double blinding (max = 20)	Measurement of effect (max = 10)	Presentation of data (max = 5)	Total score (max = 100)
GRECHO 1989	10	30	10	5	20	10	5	90
Reilly *et al* 1986	10	20	20	5	20	10	5	90
Ferley *et al* 1989	10	30	10	5	20	8	5	88
Wiesenauer *et al* 1985	5	20	20	5	20	10	5	85
Arnal-Laserre 1986	10	10	20	5	20	10	5	80
Wiesenauer and Gaus 1986	10	20	10	5	20	10	5	80
Zell *et al* 1988	10	10	20	5	20	10	5	80
Valero (Raphanus sativus) 1981	10	20	20	5	10	10	5	80
Aulagnier 1985	10	30	10	5	10	10	0	75
Wiesenauer *et al* 1983	5	10	20	5	20	10	5	75
Bordes and Dorfman 1986	10	10	10	5	20	10	5	70
Valero (Pyrogenium) 1981	10	10	20	5	10	10	5	70
Ferley *et al* 1987	8	10	10	5	20	10	5	68
Brigo 1987	10	10	20	3	10	10	5	68
Maiwald *et al* 1988	10	20	15	5	0	10	5	65
Wiesenauer *et al* 1989	5	10	10	5	20	10	0	60
Bignamini *et al* 1987	10	0	10	3	20	10	5	58
Chevrel *et al* 1984	10	10	10	3	10	10	5	58
Gassinger *et al* 1981	10	10	20	3	0	10	5	58
Ritter 1966	5	20	10	3	10	5	5	58
Wiesenauer and Gaus 1987	10	0	10	5	20	10	3	58
Lewith *et al* 1989	10	0	5	5	20	10	5	55
Savage 1977	10	0	5	5	20	10	5	55

Eighty four controlled trials scored <55 points.

[illegible]

	Score for methodology (max = 100)	Indication (No of patients/No of controls)	Intervention	Results No of patients/No of controls
Polypharmacy:				
Ferley *et al* 1989	88	Treatment of influenza (237/241)	Anas barbariae hepatis, cordis extractum C200 *v* placebo	Recovery rate within 48 hours (17·1%/10·3%)
Arnal-Laserre 1986	80	Duration of delivery (53/40)	Actea racemosa C5, arnica C5, caulophyllum C5, gelsemium C5, pulsatilla C5 *v* placebo	Duration of delivery (5·1/8·5 hours), "dystocie" (problems with dilatation) (11·3%/40%)
Zell *et al* 1988	80	Ankle sprains (33/36)	D2-D6 combination of 14 substances *v* placebo	No of patients without pain after 10 days: 28/13)
Aulagnier 1985	75	Bowel movements after abdominal operation (100/100)	Opium C9, raphanus C9, arnica C9 *v* placebo	Days until first flatus (2·5/3·2) days until first faeces (4·0/4·9)
Bordes and Dorfman 1986	70	Dry cough (30/30)	C3 combination of 10 substances *v* placebo	Very good or good result after 1 week 20/8,
Ferley *et al* 1987	68	Prevention and treatment of influenza (588/594)	D1-D6 combination of 10 substances *v* placebo	Incidence (6·5%/7·2%), duration of symptoms (7·0/6·8 days
Maiwald *et al* 1988	65	Influenza (88/82)	Aconitum D4, bryonia D4, lachesis D12, eupatorium perfoliatum D3, phosphorus D5 *v* acetyl salicylic acid 1500 mg days 1-4, 500 mg days 5-10	Positive result within 4 days (29%/23%)
Wiesenauer *et al* 1989	60	Sinusitis (45, 38, 35/34)	(1) Luffa operaculata D4, kalium bichromicum D4, cinnabaris D3 (2) Kalium bichromicum D4, cinnabaris D3 (3) Luffa operaculata D4; *v* (4) placebo	Combination score of 6 symptoms: no difference between the 4 groups,
Same formula in all patients:				
GRECHO 1989	90	Bowel movements after abdominal operation (4 groups of 150)	(1) Opium C15 (2) Opium C15, raphanus C5 *v* (3) Placebo (4) No treatment	Time until first faeces: (1) 96 hours (2) 99 hours (3) 94 hours (4) 95 hours Similar results for first peristaltic sounds and first flatus
Wiesenauer and Gaus 1985	85	Pollinosis (50/55, 59)	(1) Galphimia glauca D6 *v* (2) Galphimia glauca dilution 10 (3) Placebo	Improvement of nasal symptoms after 2, 4 weeks: (1) 60%, 78% (2) 40%, 51% (3) 41%, 58% Similar results for ocular symptoms
Valero 1981	80	Postoperative infections (54/74)	Raphanus C7 *v* placebo	No of patients with infection (15/20)
Valero 1981	70	Bowel movements after abdominal operation (43/37)	Pyrogenium C7 *v* placebo	Time until first flatus (53·3/58·6 hours
Wiesenauer *et al* 1983	75	Pollinosis (41/45)	(1) Galphimia glauca D4 *v* (2) Placebo	Improvement of symptoms after 2, 4 weeks: (1) 83%, 81% (2) 47%, 57%
Comparison of several homoeopathic treatments:				
Wiesenauer and Gaus 1986	80	Pollinosis (62, 56, 54, 53)	Galphimia glauca (1) C2 (2) C4 (3) D4 (4) LM4	Improvement of nasal symptoms after 2, 4 weeks: (1) 67%, 83% (2) 71%, 79% (3) 67%, 82% (4) 69%, 85% Improvement of ocular symptoms after 2, 4 weeks: (1) 64%, 83% (2) 73%, 88% (3) 65%, 82% (4) 76%, 89%
Isopathy:				
Reilly *et al* 1986	90	Pollinosis (74/70)	Pollen C30 *v* placebo	Change in 100 mm visual analogue scale symptom score after 5 weeks (−17·2 mm/−2·6 mm)
Classical homoeopathy:				
Brigo 1987	68	Migraine (30/30)	8 possible homoeopathic remedies C30 *v* placebo	Change in 10 cm visual analogue scale symptom score after 4 months (−6·2 cm, −0·6 cm). Similar results for frequency and duration of attacks

of indications emerged: diseases of the respiratory system (19 trials on respiratory infections, five trials on hay fever, and one on asthma); gastrointestinal complaints (seven trials); and pain from several sources (27 trials, of which six were of rheumatological diseases). Table III presents the outcome of all 107 trials. In 42 we thought that insufficient data were given to check the authors' interpretation of the outcome(s). Consequently the results reflect not our conclusions but the inference made by the authors of the publications, who to us seem sometimes to be a little overoptimistic. In most cases, however, a positive result indicates that there was a statistically significant difference in the main outcome(s) between the contrasted groups, whereas a negative result means that no significant difference was found (p>0·05). We could not pool the results statistically because of the heterogeneity of the studies.

The evidence is to a large extent positive: of the better studies 15 trials showed positive results whereas in seven trials no positive effect could be detected (in one trial only homoeopathic treatments were compared with each other). The trials with a methodological score below 55 points showed an even clearer trend: in most publications positive results were reported (66 positive, 17 negative). Overall, of the 105 trials with interpretable results, 81 indicated positive results whereas in 24 trials no positive effects of homoeopathy were found compared with (mostly) placebo controls. In the two other trials only homoeopathic treatments were compared to each other.

Discussion

In the methods section we indicated that it is possible to perform trials on the efficacy of homoeopathy, including classical homoeopathy, in a way that is acceptable for both sceptical physicians and enthusiastic homoeopaths. Criticisms of these methods, often suggesting that special methodology and statistics are needed for the evaluation of homoeopathy, are in our opinion based on lack of knowledge of research methodology.

A problem in our methodological assessment is that limited description of the methods and the results in the publication may lead to a lower score. We believe, however, that a detailed description of this information is as important as using good methodology in practice. It could be argued that other criteria should be used for the methodological assessment and that this kind of assessment is rather subjective. As stated before, we have selected well established criteria. The reader could apply different weights to the criteria to see whether substantial changes would occur in our methodological ranking, but we think that this will not be the case.

Double blinding, even if the placebo is described as indistinguishable, has to be checked by asking the patients in which group they believe that they were during the trial. Blindness must be checked early in the trial, before the treatment is expected to take effect, because positive effects would break the code. It is easy to state that a trial was double blind, but patients have many ways to break the code. This might explain small differences in favour of homoeopathy. Double blinding was not checked in any trial of homoeopathy.

TABLE III—*Clinical trials of homoeopathy grouped according to diagnoses from conventional medicine*

	Indication	Score (max = 100)	Result
Diseases of the vascular system:			
Bignamini *et al* 1987	Hypertension	58	Negative
Wiesenauer and Gaus 1987	Hypotension	58	Positive
Savage 1977	Stroke	55	Negative
Gauthier 1983	Flushing	53	Negative
Savage and Roe 1978	Stroke	53	Negative
Hitzenberger *et al* 1982	Hypertension	48	Negative
Dorfman *et al* 1988	Venous perfusion	35	Positive
Hadjicostas *et al* 1988	Bleeding	35	Positive
Master 1987	Hypertension	13	Positive
Respiratory infections:			
Ferley *et al* 1989	Influenza	88	Positive
Bordes and Dorfman 1986	Coughing	70	Positive
Ferley *et al* 1987	Influenza	68	Negative
Maiwald *et al* 1988	Influenza	65	Positive
Wiesenauer *et al* 1989	Sinusitis	60	Negative
Gassinger *et al* 1981	Common cold	58	Positive
Lewith *et al* 1989	Influenza	55	Negative
Lecocq 1985	Respiratory infections	50	Positive
Lewis 1984	Whooping cough	49	Negative
Schmidt 1987	Bronchitis	45	Positive
Chakravarty *et al* 1977	Tonsillitis	38	Positive
Mossinger 1985	Otitis media	38	Positive
Davies 1971	Influenza	35	Positive
Mossinger 1973	Pharyngitis	35	Positive
Mossinger 1982	Common cold	35	Negative
Hourst 1982	Respiratory infections	28	Positive
Mossinger 1976	Pharyngitis	25	Positive
Masciello and Felesi 1985	Influenza	18	Positive
Bungetzianu 1988	Influenza	0	Negative
Other infections:			
Valero 1981	Postoperative infection	80	Negative
Valero 1981	Postoperative infection	50	Positive
Ustianowski 1974	Cystitis	45	Positive
Mossinger 1980	Furuncles	43	Positive
Subramanyam *et al* 1990	Filariasis	38	Positive
Carey 1986	Vaginal discharge	35	Positive
Castro and Noguiera 1975	Meningitis	13	Positive
Diseases of the digestive system:			
Ritter 1966	Gastritis	58	Positive
Rahlfs and Mossinger 1979	Irritable colon	50	Positive
Owen 1990	Irritable colon	35	Positive
Rahlfs and Mössinger 1976	Irritable colon	35	Positive
Mössinger 1976	Abdominal complaints	23	Negative
Mössinger 1974	Cholecystopathy	15	Positive
Mössinger 1976	Abdominal complaints	13	Negative
Pollinosis:			
Reilly *et al* 1986	Pollinosis	90	Positive
Wiesenauer and Gaus 1985	Pollinosis	85	Positive
Wiesenauer and Gaus 1986	Pollinosis	80	*
Wiesenauer *et al* 1983	Pollinosis	75	Positive
Reilly and Taylor 1985	Pollinosis	50	Positive
Reilly *et al* 1990	Asthma	35	Positive
Recovery of bowel movements after surgery:			
GRECHO 1989	Ileus	90	Negative
Aulagnier 1985	Ileus	75	Positive
Valero 1981	Ileus	70	Positive
Chevrel *et al* 1984	Ileus	58	Positive
Valero 1981	Ileus	50	Positive
Estrangin 1979	Ileus	48	Negative
Castelin 1979	Ileus	20	Positive
Rheumatological disease:			
Shipley *et al* 1983	Osteoarthritis	50	Negative
Fisher *et al* 1989	Fibromyalgia	45	Positive
Gibson *et al* 1980	Rheumatoid arthritis	40	Positive
Andrade *et al* 1988	Rheumatoid arthritis	38	Negative
Fisher 1986	Fibrositis	38	Positive
Gibson *et al* 1978	Rheumatoid arthritis	33	Positive
Trauma or pain:			
Zell *et al* 1988	Ankle sprains	80	Positive
Brigo 1987	Migraine	68	Positive
Bourgois 1984	Haematoma	53	Positive
Casanova 1981	Myalgia	45	Positive
Pinsent *et al* 1986	Dental extraction	45	Positive
Berthier 1985	Dental extraction	40	Positive
Albertini *et al* 1984	Dental neuralgia	38	Positive
Campbell 1976	Bruising	38	Negative
Hildebrand and Eltze 1983	Myalgia	38	Positive
Hildebrand and Eltze 1983	Myalgia	38	Positive
Hildebrand and Eltze 1983	Myalgia	38	Positive
Hildebrand and Eltze 1983	Myalgia	38	Positive
Leaman and Gorman 1989	Minor burns	38	Negative
Geiger 1968	Oedema	35	Positive
Kubista *et al* 1986	Mastalgia	35	Positive
Michaud 1981	Oedema	35	Positive
Mergen 1969	Oedema	33*	
Caspar and Foerstel 1967	Oedema	28	Positive
Campbell 1976	Bruising	28	Positive
Khan 1985	Hallux valgus	15	Positive
Anonymous 1980	Cystitis	13	Positive
Mental or psychological problems:			
Delaunay 1985	Behaviour in children	48	Positive
Carlini *et al* 1987	Insomnia	45	Negative
Heulluy 1985	Depression	45	Positive
Ponti 1986	Travel sickness	40	Positive
Tsiakopoulos *et al* 1988	Vertigo	35	Positive
Vu Din San and Delauney 1983	Nervous tension	30	Positive
Dexpert 87	Seasickness	25	Positive
Alibeu and Jobert 1990	Agitation	23	Positive
Davies 1988	Aluminium deficiency	23	Negative
Master 1987	Aphasia	23	Positive
Other diagnoses:			
Arnal-Laserre 1986	Duration of delivery	80	Positive
Skaliodas *et al* 1988	Diabetes	50	Positive
Coudert-Deguillaume 1981	Duration of delivery	45	Positive
Kennedy 1971	Postoperative complications	43	Negative
Paterson 1943	Gas poisoning	41	Positive
Basu 1980	Myopia	35	Positive
Hariveau 1987	Cramps (dialysis)	35	Positive
Kirchhoff 1982	Lymphoedema	33	Positive
Kienle 1973	Respiratory insufficiency	30	Positive
Paterson 1943	Gas poisoning	28	Positive
Ventoskovskiy and Popov 1990	Complications of delivery	22	Positive
Schwab 1990	Skin diseases	20	Positive
Schwab 1990	Skin diseases	20	Positive
Mössinger 1976	Cramps (legs)	13	Negative
Khan and Rawal 1976	Verruca plantaris	0	Positive

*Comparison of homoeopathic treatments.

Although the number of trials is impressive, many questions remain. Virtually no evidence exists about the correct choice of the remedy and the potency to be used (different potencies or homoeopathic substances should be compared in controlled trials). Hahnemann's principles have been brought into practice in innumerable ways, as is indicated by the differences among the trials presented here. The process of producing preparations (the percentage of alcohol in the solution, the number of times that the substance must be shaken during potentiation, etc) and their composition (especially when herbs are used) differ greatly among manufacturers. Also, there is no plausible explanation of the mechanisms through which homoeopathy would act. Substances that contain only the solvent can have no pharmacological actions according to our present knowledge of physics and chemistry. If a homoeopath is asked his or her opinion about these mechanisms, the most likely reply is "I do not know." In practice, if a treatment works knowledge of the mechanisms of action is not necessary, and numerous examples from regular medicine can be cited in which the mechanisms are hardly understood or not at all. However, to assume that an infinitesimally diluted substance in an alcoholic solution has pharmacological effects would mean that essential concepts of modern physics would have to be dismissed.

An important problem in reviewing the literature is publication bias. Especially with a controversial subject such as homoeopathy, several problems may exist. More trials with positive results might have been submitted and accepted by "alternative" journals, whereas small trials with negative results might not have been submitted or might have been rejected. On the other hand trials with positive results might have been rejected and negative trials more readily accepted by "regular" journals. About one third of the trials were published in each of regular journals, alternative journals, and by other means of communication (proceedings, reports, dissertations, books). No relation between the result and the place of publication was seen. Negative results were reported in alternative journals 12 times, in regular journals seven times, and in other publications five times. When talking to authors of trials we identified at least six trials for which no manuscript had been submitted for publication. It is difficult to discover the true reasons for failure to submit an article for publication, but we think that the (possibly negative) results may have been an important factor in these cases.

Nevertheless, much evidence is available. We tried to decrease the effects of publication bias by extensively checking every possible source for publications or reports of trials. We wrote to many researchers and also visited several of them to learn whether there were any unpublished trials and to get further details of the published ones. We used strict criteria to select the best trials and based our main conclusions on the results of these. The amount of positive evidence even among the best studies came as a surprise to us. Based on this evidence we would be ready to accept that homoeopathy can be efficacious, if only the mechanism of action were more plausible. The way in which the belief of people changes after the presentation of empirical evidence depends on their prior beliefs and on the quality of the evidence.[illegible] Critical people who did not believe in the efficacy of homoeopathy before reading the evidence presented here probably will still not be convinced; people who were more ambivalent in advance will perhaps have a more optimistic view now, whereas people who already believed in the efficacy of homoeopathy might at this moment be almost certain that homoeopathy works.

A trial of very high quality was that of the Groupe de Recherches et d'Essais Cliniques en Homéopathie, financed by the French Ministry of Social Affairs and performed by a group consisting of regular and homoeopathic researchers.[illegible] After the earlier publication of several trials in which homoeopathy was shown to decrease the time to recovery of bowel movements after abdominal surgery, this hypothesis was retested in a rigorous trial comparing four groups of 150 patients (two groups were treated with opium C15 and raphanus C5, one group with indistinguishable placebo, and one group was not treated). No differences at all were found. Will more of such trials for other indications show the same results and refute the existing evidence?

The weight of the presented evidence will probably not be sufficient for most people to decide definitely one way or the other. The question arises, What further evidence would be needed? Investigations in animal or plant models may increase the belief of sceptical people before they have read the evidence from clinical trials, but if no positive results are found homoeopaths may claim that homoeopathy only works in humans. We did not assess the evidence from such investigations; Scofield concluded in 1984 in a comprehensive review article that "despite the great deal of experimental and clinical work there is only little evidence to suggest that homoeopathy is effective. This is because of bad design, execution, reporting or failure to repeat experimental work."[illegible] If more (well performed) controlled trials in humans are demanded, cooperation between sceptical investigators and homoeopaths is likely to make the trial results more convincing for many readers. The question is how many of such trials would be needed to draw definitive conclusions? The evidence presented in this review would probably be sufficient for establishing homoeopathy as a regular treatment for certain indications. There is no reason to believe that the influence of publication bias, data massage, bad methodology, and so on is much less in conventional medicine, and the financial interests for regular pharmaceutical companies are many times greater. Are the results of randomised double blind trials convincing only if there is a plausible mechanism of action? Are review articles of the clinical evidence only convincing if there is a plausible mechanism of action? Or is this a special case because the mechanisms are unknown or implausible?

In our opinion, additional evidence must consist of a few well performed controlled trials in humans with large numbers of participants under rigorous double blind conditions. The results of the trials published so far, and the large scale on which homoeopathy is brought into practice, makes such efforts legitimate.

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Acute myeloblastic leukaemia—a model for assessing value for money for new treatment programmes

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Abstract

Objective—**To measure the effects of changes in treatment of acute myeloblastic leukaemia that may give better value for money.**

Design—**Retrospective analysis of patients' notes to identify items of management costing money; prospective costing of these items. The Medical Research Council acute myeloblastic leukaemia 9 trial was used to identify the amount and distribution of these costs when either one or two courses of induction treatment were required to obtain complete remission. These findings were then extrapolated to four published international controlled trials using similarly intense treatment and in which the number of courses of treatment required for complete remission was stated, to compare British costs for treatment with idarubicin and daunorubicin, both in combination with cytarabine.**

Setting—**Leukaemia unit, Royal Marsden Hospital, London.**

Subjects—**Data on 10 patients receiving intensive induction treatment for acute myeloblastic leukaemia were used to identify 160 items of cost in four broad groups: general (including accommodation), diagnostic, supportive treatment, and cytotoxic chemotherapy. One newly treated patient was prospectively assessed over one month, including a time and motion study, to cost these items; then costs for 268 patients from the MRC trial receiving moderate induction chemotherapy including daunorubicin were assessed, and costs for treatment of 522 patients in the four international studies comparing daunorubicin with idarubicin were analysed.**

Main outcome measures—**Cost effectiveness was measured as the overall cost to obtain complete remission in untreated patients with acute myeloblastic leukaemia after treatment with idarubicin or daunorubicin.**

Results—**The 160 costed items were measured for their sensitivity in varying the total cost of treatment, this being assessed within Britain in other district general and private hospitals to measure the extremes of cost of these items. Overall, idarubicin, although more expensive, showed a substantial saving (£1477 per patient) in total hospital costs, more than offsetting the increased cost (£607) of the new treatment, an overall saving of £870 per patient (5%).**

Conclusion—**Approaches modelling cost effectiveness may be an essential part of planning new programmes of treatment in the future. This method can be used to estimate the cost effectiveness of the treatments in different environments and countries where costs may vary widely.**

Introduction

After the publication of the government's white paper *Working for Patients* there has been widespread debate on the economic aspects of health care policy. Although in a broad economic analysis total costs and benefits for the whole national economy and for individual patients should be considered, at present only costs and effectiveness within the NHS can be assessed, and it is these that this paper considers.

Improvements in survival of patients treated for acute myeloblastic leukaemia have resulted primarily from the development of more intensive treatment regimens, improved supportive care, and marrow transplantation.[1] The standard initial treatment for induction of remission of acute myeloblastic leukaemia is one or two courses of a combination of an anthracycline (for example, daunorubicin) and cytarabine. Both drugs have been available for many years and are fairly inexpensive. If we use as the end point patients who achieve complete remission (are well and have no detectable disease) on one relatively expensive course of treatment then this may cost less overall and be more cost effective than patients attaining remission in two cheaper courses but requiring extra time in hospital.

The International Homeopathic Renaissance

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by

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Summary: This article gives a brief look at the history and recent development of homeopathy in Europe, India, the Soviet Union, and America.

Key words: Homeopathy, History, Europe, Soviet Union, India, America

Introduction

Since its inception 200 years ago, homeopathy has attracted support from European royalty, the educated elite, and leading artists. It was thus no surprise that the most expensive painting ever sold was a portrait of a homeopathic physician, Dr. Gachet, drawn by her personal friend and patient, Vincent van Gogh. Although homeopaths use exceedingly small doses of medicines, it seems that people greatly value portraits of them. In this case, the portrait of Dr. Gachet sold for $ 82.5 million [1].

Homeopathy is considerably more popular abroad than it is in the United States. Homeopathy's popularity in Europe and Asia is particularly impressive.

The Explosion of Homeopathy in Europe

According to recent surveys in France, an astounding 30% of the French public have used homeopathic medicines, and 32% of French family physicians have prescribed them [2]. At least six French medical schools offer courses leading to a degree in homeopathy, and homeopathy is taught in all pharmacy schools and in four veterinary schools [3].

In a prominent French news magazine President François Mitterand and six medical school deans called for more research on homeopathy, and the author of this article editorialized, "It is a fact that homeopathy obtains results, sometimes spectacular results"[4].

One further bit of evidence for the growing acceptance of homeopathic medicines as household items in France is that the most popular cold and flu medicine is not Contact or any other conventional drug: it is a homeopathic remedy [5].

Homeopathy is not as popular in England as it is in France, but according to an article in the British Medical Journal, 42% of British physicians surveyed refer patients to homeopathic physicians [6]. Another survey of British physicians discovered that 80% of recent graduates wanted training in either homeopathy, acupuncture, or hypnosis [7].

The Scots hate to be overshadowed by the British, and this is also true in homeopathy. According to *The Times of London*, homeopathy is now the fastest growing alternative therapy in Scotland. The number of Scots who have used homeopathic medicines has more than doubled from 1985 to 1990, increasing from 5% to 11%. Similarly, in 1985 about 23% of those Scots interviewed in 1985 said they would "seriously consider" going to a homeopath, and in 1990 this figure grew to 40% [8].

Homeopathic medicine is very popular in Germany as well. One respected author estimated that 20% of German physicians use homeopathic medicines occasionally [9]. At present, the most popular hay fever remedy in Germany is a homeopathic medicine, and other homeopathic medicines for the common cold, sore throat, and circulatory problems are in the top ten of their respective categories [5].

To further aid the growth of homeopathy, the former President of Germany, Prof. Karl Carstens, and his wife, Dr. Veronica Carstens, who is a medical doctor and homeopathic physician, recently started a foundation for homeopathic research [10]. Numerous new research efforts in Germany and throughout Europe have begun in the past few years.

It is also interesting to note that homeopathy is gaining such respect in medical and business circles that one of the leading German homeopathic manufacturers is owned by the same company that owns the BMW car company.

In addition to homeopathy's popularity in France, England, Scotland, and Germany, it is also very popular in the Netherlands, Belgium, Austria, and Greece.

Homeopathy Goes Mainstream in India

Despite homeopathy's impressive popularity in Europe, it is even more popular in India. Presently, there are over 100,000 homeopathic doctors and over 100 four- and five-year homeopathic medical colleges in this country. Considering how many more trained homeopaths there are in India compared to the U.S., perhaps one day India will send a Peace Corps team of homeopathic physicians to America.

Homeopathy has achieved such respect that in 1987 the government established homeopathic drug detox clinics in six different police stations in New Delhi. A recent conference in India, which described impressive results in the homeopathic treatment of drug addiction, received accolades from India's Minister of Health and Family Welfare, the Finance Minister, and the Chief Justice [11]. In addition to the Indian government's support of homeopathic drug detox clinics, it has also supported various research projects and homeopathic hospitals and clinics.

Even Mother Teresa, who for many decades has served India's poorest citizens with medical care, has added homeopathic care to the services offered at her missions. Mother Teresa has a special interest in homeopathic medicine because of its effectiveness and low cost.

At present, four charitable homeopathic dispensories are run under the guidance of the Mothers Missionaries of Charity. One of these dispensories primarily provides homeopathic medicines to poor and sick children in Calcutta, while the other three provide homeopathic medicines to anyone who needs them. Considering the serious health problems that poor people in India experience, it is truly miraculous that homeopathic medicines are so effective as the primary method of treatment for many children and adults.

Mother Teresa opened her first charitable homeopathic dispensory in Calcutta in 1950. She is known to sometimes prescribe homeopathic medicines herself.

Dr. (Sister) M. Gomes, a physician who has worked at the Mothers Mission in Calcutta since 1945, notes that one of the obstacles to the spread of homeopathy in the Mothers' work is inadequate funding for homeopathic hospitals.

Homeopathic Perestroika in the Soviet Union

Homeopathy is even relatively popular in the Soviet Union [12]. Although there are only about 500 homeopathic physicians, they are popular enough that most of them charge for their services. Since most Russians receive free conventional medical care, it is indeed a tribute to homeopathy that a growing number of Russian citizens are paying for homeopathic care.

Because Russian homeopaths charge for their services, they have become part of the new entrepreneurial "perestroika" that is currently taking place.

Even Izvestia recently published a series of articles on homeopathy in which they reported that a homeopathic clinic established for factory workers in 1984 resulted in a 10.1% decrease in days lost due to sickness. The series of articles concluded with an editorial that advocated further support for homeopathy from the Ministry of Health.

As a further sign of homeopathy's growing acceptance, President Gorbachev awarded a medal to Dr. Demyan Popov for his work in popularizing homeopathy in the USSR.

Homeopathy is also relatively popular throughout South America, especially in Brazil and Argentina. Homeopathy has become a bit of a legend in Argentina because its greatest hero in the 19th century, General San Martin, was known to carry a homeopathic medicine kit when he travelled.

Homeopathy is also quite popular in Mexico, where there are five homeopathic medical colleges, including two in Mexico City.

Homeopathy in America

At the turn of the century there were over 20 homeopathic medical schools in America, including Boston University, University of Michigan, University of Minnesota, and Hahnemann College in Philadelphia. There were also over 100 homeopathic hospitals and over 1,000 homeopathic pharmacies. In 1900 homeopathy was more popular in America than anywhere else in the world [13].

However, as the result of a concerted effort by the American Medical Association and the drug companies, homeopathy went into a sharp decline. By the 1950s there were fewer than 200 homeopathic physicians.

Although homeopathy in America is presently lagging behind the rest of the world, Americans hate being second to anybody. Luckily for us all, homeopathy is growing at an extraordinary rate. According to the F.D.A., sales of homeopathic medicines grew by 1,000% from the late 1970s to the early 1980s [14]. According to *The Washington Post*, the number of physicians in the

United States who specialize in homeopathy doubled from 1980 to 1982 [15].

In the past two years homeopathy has received more media coverage than it has in the past 50 years. More research on homeopathy has also stimulated its growth, and more and more new books have been published, updating old homeopathic knowledge.

Homeopathy may be more popular in other countries, but because America is just waking up to homeopathy's impressive healing potential, we can all expect a tremendous resurgence of this marvelous healing art and science.

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TESTIMONY OF MR. LARRY HARRIS, JR.

APRIL 9, 1992

JOINT HEARING ON MEDICAL QUACKERY

BEFORE

SMALL BUSINESS SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES ENERGY

AND,

AGING SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE

I Larry Holmes, Jr. am writing this concerning my experience with Dr. Evans Rapsomanikis at the Paradise Pain Clinic in Las Vegas, Nevada.

On March 29 in the late evening I dove in the lake here in my home town, Dexter Lake. The water was too low and I broke my neck when I hit the sandy bottom. I was taken to Sacred Heart Hospital where they operated on me and saved my life but I woke up the next morning completely unable to move and I couldn't understand why and didn't want to be this way after a week on the table that rolled back and forth with metal in my head to keep me still. I ended up down stairs in rehabilitation at Sacred Heart. The doctors all told me I was doing good but I was a C-4-5-6 incomplete Quad. I would never be able to walk or move again.

At that time, my mom told me about a Dr. Rapsomanikis in Las Vegas that had called and talked to her at the hospital and again at home a couple of times. He told her that he had a clinic in Las Vegas, Nevada and also in California where he had helped a football player like me to walk again. That same man was now going to college and married and doing fine. He said he could and would help me to walk again. He told me to get well and call him when I left the hospital and fly to Las Vegas to the clinic. So when I was released from Sacred Heart about in June he called me at my brothers house and told me he could make me walk again without any doubt if I came to the clinic for about 4 to 6 weeks of treatments.

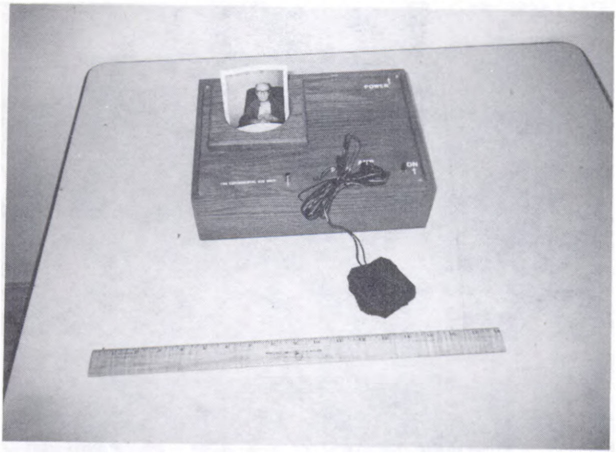
I was only 21 years old and at that time my family and I would have done anything to help me walk again or even move a little. So when this doctor told us he would and could help me if I'd come down. I was unaware of the complications involved in my inquiry. I only wanted to get out of this chair and walk. There is nothing you won't do to get your life back or give up. So my family made the arrangements for the trip down to the clinic, the motel rooms and plane tickets. My mom and dad drove and met the doctor and had a tour of the clinic. Once again the doctor told them he could help me but it would take 4 to 6 weeks of treatments 6 days a week, 2 hours a day. So they got 2 motel rooms by the clinic for the family because it took my 2 brothers and parents to help take care of me there. Plus they rented a special hospital bed for me and then I flew down there with my brother and sister-in-law on the plane.

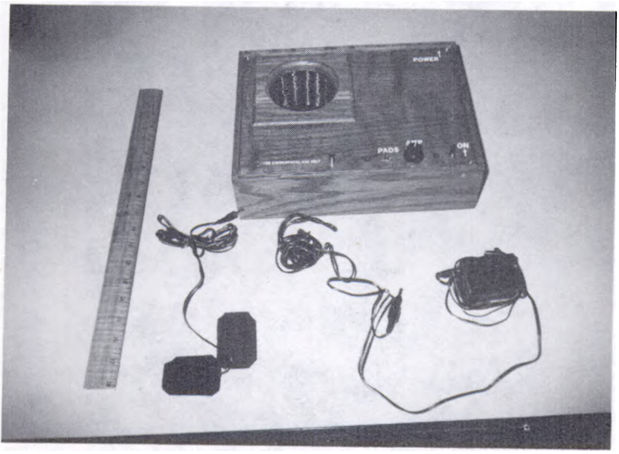
The next day I met Dr. Rapsomanikis at the clinic with my family. He once again said to me without a doubt that I would walk out of there and drive myself home. He said he would provide 100 percent recovery of my injury. I was taken into a small room with a large type chair with a small machine beside it. Out of the chair there were wires which they put on my ankles, legs, arms and my back. He said that the machine put energy into my spinal cord slowly and it would allow the body to repair my spinal cord. It was called the Bio Ionic system and I was to swim in the motel pool every day. I took the treatments every day, 2 hours a day for about 7 days. Every day he would tell me the next day another doctor would be seeing me. But every day he'd change the time to the next day. I never saw any doctor but him. He came in at the end of each day and put either ice or a pin on my feet and my toe or foot would move. Then he'd say, "See it's starting to work for you, you are going to walk."

My parents could see no improvement after about 20 treatments and decided we wouldn't stay any longer. The same day we went home. We were gone about 3 weeks. After I got home I couldn't bring myself to believe any one. I didn't want to see any doctor, go to rehab or even live the way I was. It took me a year to come out of it and start from the beginning again to want to live again, to try rehab or even talk to the doctors here.

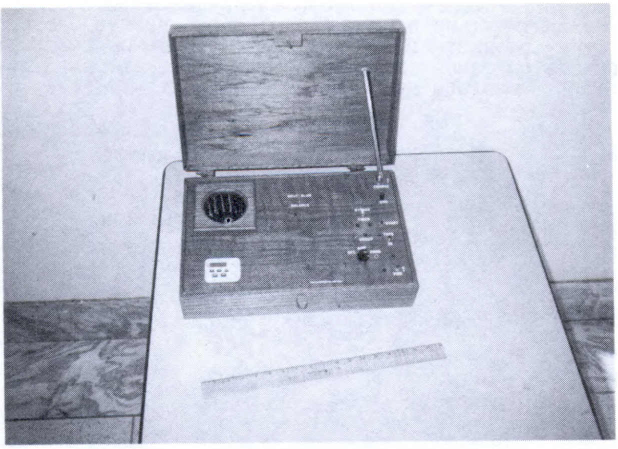
I am doing good now. As good or maybe better than a quad should do but thanks to the doctor at the clinic I lost a year of my life and almost my life. What I am trying to say is no one should be able to take a persons life and turn it upside down as he did mine.

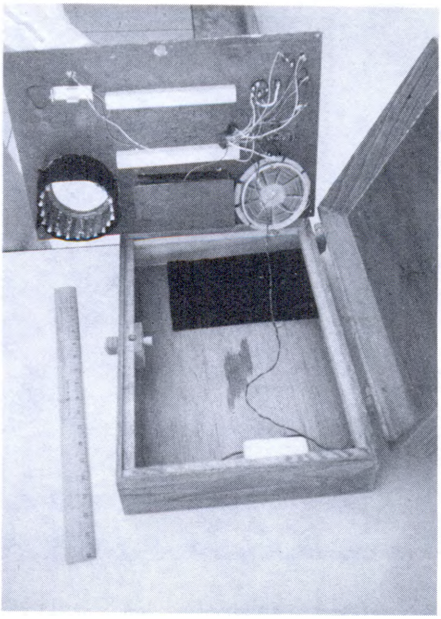
THE FOLLOWING PHOTOGRAPHS ARE OF VARIOUS "EXPERIMENTAL" DEVICES CONFISCATED BY THE OFFICE OF THE ATTORNEY GENERAL OF IDAHO AND DEMONSTRATED TO MEMBERS OF CONGRESS AT THE JOINT SUBCOMMITTEE HEARING ON DUBIOUS MEDICAL DEVICES, APRIL 9, 1992



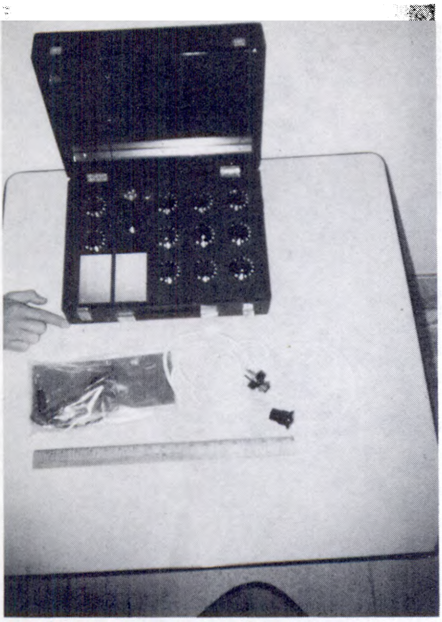


THE "SWEEP PULSE RESONATOR" REFERRED TO BY CHAIRMAN WYDEN IN HIS OPENING REMARKS

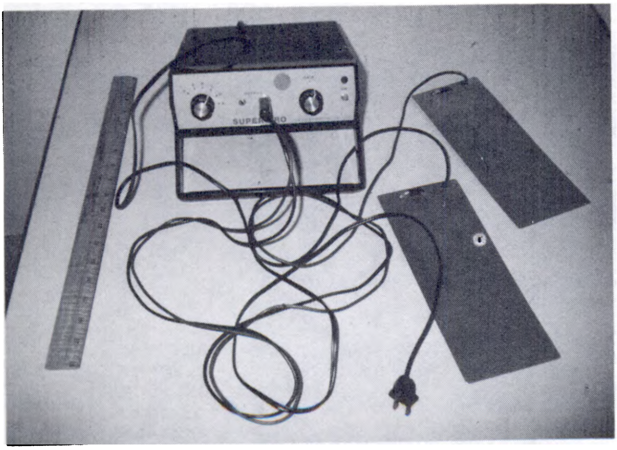




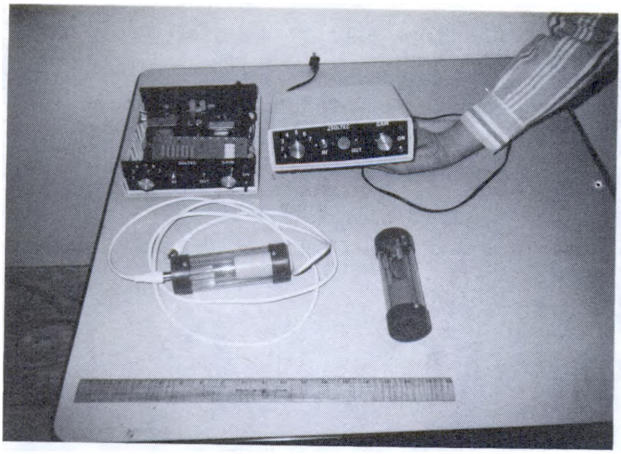
A MORE ELABORATE "SWEEP PULSE RESONATOR" AND A PHOTOGRAPH OF IT INTERNAL WIRING AND MACHINERY



THE "GRANDFATHER" OF THE "SWEEP PULSE RESONATORS" REFERRED TO BY RANDALL EVERITT OF THE OFFICE OF THE IDAHO ATTORNEY GENERAL



THE "SUPERPRO" DEVICE REFERRED TO BY INSPECTOR EVERITT



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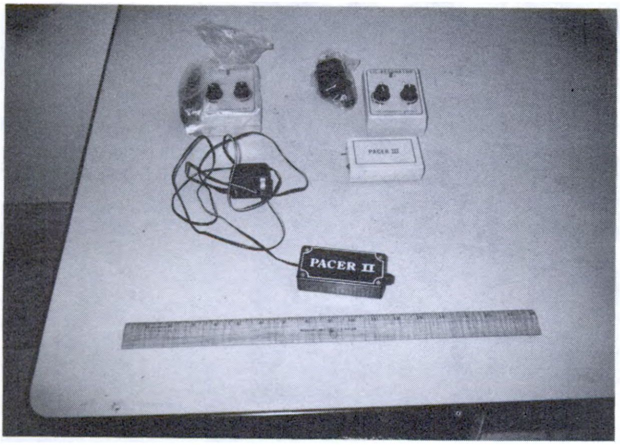
PACER II
PACER III

VARIOUS PORTABLE "RESONATOR" DEVICES CONFISCATED BY THE IDAHO ATTORNEY GENERAL

Congressmen Wyden and Lancaster and Cathy Gardner, staff director, Aging Subcommittee on Health and Long-Term Care, examine quack medical devices.

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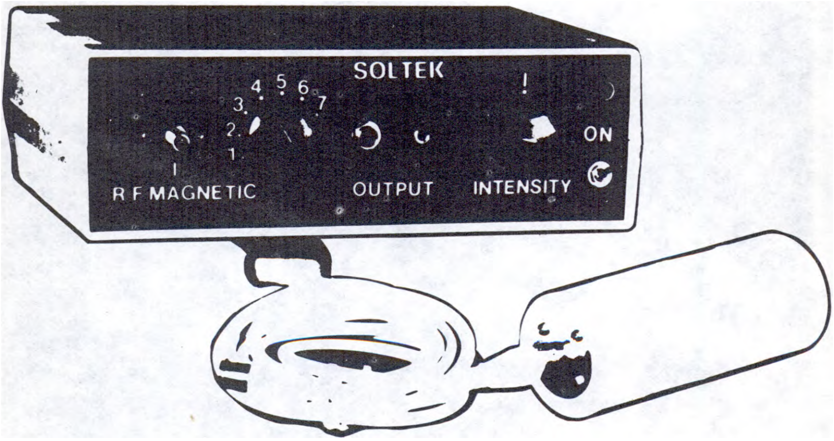
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OUTPUT
INTENSITY
ON

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PHONE (208) 733-9591

The present line of pulse generating equipment is designed and manufactured for research persons for investigation and educational study of pulse energy on plants, animals, and humans. This type of equipment is not intended for the specific treatment of any disease in animals or humans, but may be used for the study of the effects of pulse stimulation.

PLEASE NOTE

NO MEDICAL CLAIMS ARE MADE OR IMPLIED IN THE USE OF THESE DEVICES. FEDERAL LAW PROHIBITS THE USE OF THIS TYPE OF EQUIPMENT FOR THE TREATMENT OF DISEASE.

WHAT IS A RESONATOR?

Resonance is the reinforcement or intensification of electrical vibrations. As an example, mount two tuning forks of the same pitch with the open ends facing each other. If one is struck with a soft mallet then quickly silenced by grasping the prongs with one hand, the other fork will be found to be sounding loudly enough to be heard over a large room. They come into sympathetic vibration—*resonance*—with one another.

Like the resonance of the tuning fork, all "matter" (molecules and atoms) in the universe is electrical and is vibrating at a specific vibration characteristic of the substance, producing minute oscillating currents. When an electrical signal is producing an oscillation and this energy strikes a molecule of matter that is tuned to the same frequency, it will cause the matter to oscillate in sympathetic vibration. If the electrical configuration of the matter is out of electrical balance (not at its natural frequency and intensity) we believe that the proper electrical oscillating signal will stimulate it to cause it to come into sympathetic vibration and be restored to its equilibrium or natural resonance.

Pioneers in experimentation with this theory using electrical oscillators—such as Dr. Albert Abrams (who may have been the first) in 1915, his protege Dr. Ruth Drown, Georges Lakhovsky, and many others who followed—were successful in experimental demonstrations with the principles of electrical resonance.

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ED SKILLING

ED is a retired Aerospace and Sound Engineer with 50 years experience in the field of mechanical and electronic engineering. In 1928 Ed began his career building crystal sets in the early days of Radio Technology and also experimented in sending pulses of electrical energy in his body using a model T spark coil which was the start of his interest in electro-medicine.

With time out for WORLD WAR 2, ED continued his research in the field of electro-medicine and electronics from crystal sets to gaseous tube laser technology to this point of time,1989.
After spending 45 years of work in the corporate structure of Aerospace,ED retired to spend full time in research.In 1983 a company called E.F. SKILLING INC. (named after a family member) was founded in Southern California to market experimental devices for the medical industry. ED turned the operation of the business over to family members and has devoted his energy to the research of inovative electronic circuitry and is now involved in full time consulting with medical equipment companies and doctors in the health-care industry for the advancement of electro-medicine.
ED is currently developing new experimental designs using modulated high RF FREQUENCY PROBES and laser technology.

DR. JAMES SOLOMON

DR. SOLOMON, A PIONEER IN ELECTRO MEDICINE, STARTED IN THE ELECTRONIC FIELD AS A RADIO OPERATOR ON MERCHANT SHIPS DURING WORLD WAR II. HE HELPED INTRODUCE LASERS IN THE U.S. WITH THE LIETZ COMPANY.

DURING THE LAST 10 YEARS, HE HAS BEEN WORKING IN THE EXPERIMENTAL TEN'S UNIT FIELD. DR. SOLOMON IS A GRADUATE OF BRIGHAM YOUNG UNIVERSITY, THE ARIZONA COLLEGE OF NATUROPATHIC MEDICINE, AND IS PRESIDENT OF THE IDAHO ASSOCIATION OF NATUROPATHIC PHYSICIANS.

HE IS ALSO PRESIDENT OF THE IDAHO HOMEOPATHIC MEDICAL ASSOCIATION, AND SECRETARY OF THE AMERICAN NATUROPATHIC MEDICAL ASSOCIATION.

ELECTRONIC MEDICINE

The way we have helped people heal themselves the the past has been with the use of Herbs and Homeopathic Items. When you look at these, what we have really been giving our patients is the energies of these items.

The metabolic activity of the cell is an expession of the dynamic inter-relationship of chemical and electrical reactions, many of which are concerned with the liberation, interchange, or utilization of free body energy.

Our job as healers is to balance the body energies so that the body can then heal itself.

The use of chemicals may set up a counter detrimental reaction that may times results in improper balance of the body chemistry and body energies. Man is an electronic mechanism. the depletion of these body energies cause weakness and death.

Since all matter is electrical in nature, and since, in the final analysis, all energy is radiant and electrical energy, then all protoplasm is a system of generators, conduction lines, dialectrics, and capacitors in the living cells producing and holding body electrical changes.

The chemical constitution of the body is definately affected by the rays and frequencies of electrical currents. We must use in practice proper frequencies and electrical stimulation, as the body must affect its own cure. All we can do is help the body heal itself.

By stimulation of the cells of the body by proper electronic frequencies, circulation will be greatly increased. Ozone and oxygen in the body with the process of exidation stimulation will aid greatly in the elimination of toxemia. If the electricity applied synchronizes with the natural cell, energy of the body itself becomes an actual part of the oxygen generator.

When the object is to restore health, to save life and suffering, why not use the method nature does, which originates in the solar system and the universe. Let it be remembered life and body radiant energy are akin to each other. Without proper radiant energy and electrical energy, life cannot be maintained.

One cannot guess, one must know which rays and frequencies are best for the heart, liver, muscles and other parts of the body. You must know which frequencies are best.

In the past and present many of the so called Tens Units on the market are using the wrong frequencies and wave forms, and sometimes beat the organ or problem and make it worse. This is the problem that square wave Tens Units cause.

For example, if you want to affect a person adversly, you would do the following using a square wave Tens Unit:

At 6.66 hertz we find depression in mice

At 3.21 hertz cancer is caused in mice

At 10.8 hertz a person can be made nervous and edgy

At 13.0 hertz you can cause someone to be uptight and and angry with a lot of stress

At 15.0 hertz you can cause someone to be violent and angry.

At 1840 hertz it has been found to stimulate growth of cancer

At 1989 hertz it has been observed to grow cancer

The above is with the square waves. This does not apply to spike waves, the type of instrument developed by Ed Skilling.

The 15.0 hertz square wave is one of the frequencies the USSR (Russia) has been hitting our country with to upset our population. (Sometimes called the Russian Woodpecker. You can listen to it on most short wave radios.)

Also, at 30 hertz broadcasting along with scalar waves is used to upset our populace and our weather patterns. Further information of this is available upon request.

If you use the wrong frequencies, you can, like most computer terminals, cause premature abortions--lower sperm count. Another problem found in the last few years has been that electronic instruments, fans, air conditioners, autos and powerlines, emit frequencies which may have caused the average sperm count in tests to drop 50% in the last 20 years.

SOL TEK
TENS UNIT

NO MEDICAL CLAIMS ARE MADE OR IMPLIED IN THE USE OF THIS DEVICE. FEDERAL LAW PROHIBITS THE USE OF THIS TYPE OF EQUIPMENT FOR THE TREATMENT OF DISEASE. IT CAN BE USED ONLY FOR INVESTIGATION AND EDUCATIONAL PURPOSES AS THIS INSTRUMENT IS AN EXPERIMENTAL RESEARCH DEVICE.

THIS TENS UNIT IS USED ONLY AS AN INVESTIGATIONAL TOOL, IT IS AUTOMATED AND REQUIRES NO TRAINING BEYOND THE INSTRUCTIONAL PROVIDED.

A FULL ONE YEAR WARRANTY IS INCLUDED WITH THE PURCHASE OF THIS RESEARCH INSTRUMENT.

DESCRIPTION OF UNIT

THIS UNIT CONSISTS OF 4 PARTS:

1. ONE LARGE SET OF PADS
2. ONE R.F. MAGNETIC COIL
3. ONE R.F. CONNECTOR CABLE
4. ONE FRQUENCY GENERATOR

TENS UNIT: INSTRUCTIONS FOR USE

CONNECT THE WHITE R.F. CABLE TO THE COIL AND TO THE GENERATOR. BE SURE TO CAREFULLY ALIGN THE CENTER CONDUCTOR TO THE THREADED CONNECTOR AT EACH END. PUSH THE CABLE ONTO THE THREADED R.F. CONNECTORS. (AS YOU WOULD ON A TELEVISION SET). THE LARGE PADS ARE FOR THE FEET AND BODY AND SHOULD BE WET WITH PURE WATER. PLACE WET WASH CLOTH OVER PADS AND PUT FEET ON PADS. USE ON THE FEET CAUSES EQUAL INTENSITY OVER THE WHOLE BODY.

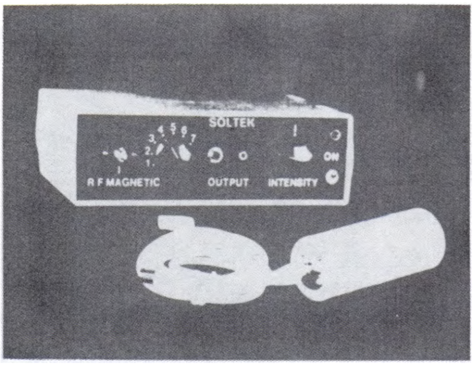
THE PROBE OR CYLINDER OPERATES A CARRIER FREQUENCY OF 5,000,000 HTZ AND SHOULD BE PLACED ON THE SKIN IN PROBLEM AREAS. THIS GIVES A GREATER PENETRATION OF THE BODY THAN THE TRANSCUTEOUS METHOD OF PADS ON THE SKIN. PADS AND PROBE SHOULD BE USED AT THE SAME TIME. EFFECTIVE PENETRATION IS IN A CONE PATTERN WITH COIL OF 2-3 FEET, FROM END OF COIL. USE END ONLY ON SKIN. THE COIL SHOULD NOT BE USED MORE THAN 30 MINUTES IN ONE 24 HOUR PERIOD.

THE SETTINGS ON THE 7 DIALS CAN BE USED TWICE A DAY AND CAN BE BE USED FROM 3 MINUTES TO 10 MINUTES ON EACH SETTING.

PAGE 2

CAUTION: USE PROBE ONLY ONCE A DAY AND NOT FOR MORE THAN 30 MINUTES. UNIT CAN BE USED WITHOUT PROBE. IF USED FOR A SECOND TREATMENT, DO NOT USE COIL OR PROBE.

THE SUGGESTED USE OF THE SOL TEK IS FOR RESEARCH PURPOSES ONLY. ANY FINDINGS ON YOUR RESEARCH PROJECT WOULD BE GREATLY APPRECIATED BY THE MANUFACTURER.


SOLTEK
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R F MAGNETIC
OUTPUT
INTENSITY
ON

EXPERIMENTAL USES OF THE SOL TEK

TIMES IN MINUTES

WP: WITH THE PROBE COIL

		MACHINE DIAL SETTINGS						
PROBLEM	# of times	1	2	3	4	5	6	7
ABCESS	10	5	6	9 wp		8 wp		9 wp
ACIDOSIS	7	6	6 wp	8		6 wp		8 wp
ACNE	11	9	11 wp	5		8 wp		7
ACUTE SHOCK	9	11 wp	6 wp	7	5 wp	6 wp	3	3
ADDISON'S	14		7	11 wp				
ADRENALS	8	6	8 wp	9				9 wp
AIDS	19	9	11	16 wp	8 wp	7 wp	6	
ALLERGIES	7	10 wp	9	10 wp				
AMENORRHOEA	11					6 wp		
ANGINA	11			7 wp				
ARTHRITIS	17	12	13	11 wp		8 wp		
ASTHMA	8	11	10	8 wp	5 wp			
AUTO INTOXICATION	12	8	9 wp					
BACCILUS	6	8 wp	11 wp		9 wp	4		
BACTERIUM	8	6 wp	8	10 wp	8	7 wp		
BELL'S PARALYSIS	9	8 wp	10 wp	6 wp				
BILIOUSNESS	11	6	9 wp	10 wp		7 wp		
BLADDER	6	5	8	9	8 wp			
BLOCKAGE	12	7	6	9 wp	9 wp			
BLOOD CLOTS	13	4	4 wp	7 wp	5	8 wp		
BOTULISM	6	3	8 wp	4				
BRAIN	13	6	7	10 wp		7 wp		
BRAIN TUMORS	16	8	11	13 wp	7	8 wp		
BRONCHITUS	11	11 wp	12 wp					
BURSITIS	12	6	8	11 wp				
CANCER	22	9 wp	13	9 wp	11 wp	10 wp		
CANDIDA	12	8 wp	11 wp	8	9 wp	8 wp		
CATARACT	10	14 wp	6	7				
CELLULITES	14	8 wp	4 wp					
CEREBRAL PALSY	8	11	7 wp	8	12 wp	9		
CHANCRE	13	11	13 wp	5		11 wp		
COLD	4	13 wp	8 wp	5		11 wp		

EXPERIMENTAL USES OF THE SOL TEK

TIMES IN MINUTES WP: WITH THE PROBE COIL

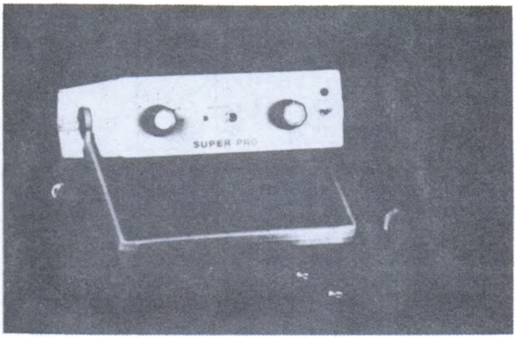
		MACHINE DIAL SETTINGS						
PROBLEM	# of times	1	2	3	4	5	6	7
CHICKEN POX	9	7	12 wp	6 wp				
CIRCULATION	14	8 wp	8 wp				7	7
CIRHOSIS	13		5	14			9 wp	8
CHLAMYDIA TRACHOMATIS	7	9 wp	8 wp	8 wp		8 wp		8 w
COLITIS	10	8 wp	9 wp	10				
COMA	11	14 wp	8	9				
CONVULSIONS	12	7 wp		7 wp			11	10
CYSTITIS	15	5 wp	11 wp	6	8 wp	9 wp	4	7
DEGENERATION	5	5	6 wp	9 wp	8	10 wp	5	6
DELIRIUM TREMENS	16	6	8 wp	9 wp				
DERMATITIS	11	13 wp	4	6				8 w
DETOXIFICATION	6	6 wp	6 wp	6 wp			6	6
DIPTHERIA	6	3	4 wp	12 wp	3	4	5	6
DISTEMPER	3	8	10 wp	6			4	4
DOWN'S SYNDROME	8	4	6 wp	6 wp			7 wp	6 w
EAR INFECTIONS	5	8	4	8 wp		9 wp	7 wp	5
EMPHYSEMA	9	5 wp	4 wp			9 wp	7 wp	
ENCEPHALITIS	11	8 wp	5	6 wp			3	4
ENDOMERITIS	6	10 wp	8	11 wp	6 wp		3	4
FIBROSIS	14	4	9	8		7 wp	7 wp	
FUNGUS	10	6 wp		11 wp				8
GALL BLADDER	4	3 wp		6 wp				
GANGRENE	15	4	9 wp	10 wp		11 wp	4	5
GIARDIA LAMBLIA	8	10 wp	12	13 wp	11 wp		7	9
HEART	6	5 wp	6 wp					
HEPATITIS	18	14 wp	7	17	10 wp	8 wp	5	9
HERPES	13			17 wp	7 wp	9 wp	12	14
HODGKIN's	12	4	9	12 wp			13 wp	
HYDROPHOBIA	4	9 wp	11 wp	8 wp			5	7
INFLUENZA	6	7 wp	15 wp			8 wp	4	6
LYMPHATIC	9	11	6					

EXPERIMENTAL USES OF THE SOL TEK

TIMES IN MINUTES WP: WITH THE PROBE COIL

PROBLEM	# of times	MACHINE DIAL SETTINGS						
		1	2	3	4	5	6	7
MASTITIS	9	12 wp	6	8 wp	6 wp	8 wp	7 wp	
MEASLES	5	9 wp				8 wp	8 wp	9 wp
MENIERE'S	6	5	11 wp				3	2
MENINGITIS	18	17 wp				10 wp	12 wp	14 wp
MONONUCLEOSIS	6	10 wp	11 wp					10
MUMPS	3	14 wp	9 wp	6			8	9
MULTIPLE SCLEROSIS	14	6 wp	11 wp	15	12 wp	9 wp	4	7
NEOPLASMS	15	8 wp	13 wp	14	6	9 wp	9	3
NEURITIS	8	7 wp	11 wp	6			4	4
OSTEOMYELITIS	20	12 wp	8 wp	6 wp			9	10
PHLEBITIS	11	10 wp	6	8 wp			4 wp	7
PNEUMONIA	7	16 wp	4	5		9 wp		
PROSTATE INFECTION	4	9 wp	10 wp	6 wp				8 wp
PSORIASES	5	7	8 wp	12 wp		10 wp	11	11
PUS	13	14 wp	5	5		12 wp	13 wp	4
RABIES	5	11 wp	4	10 wp			8 wp	12 wp
RHEUMATISM	16	8	14 wp	5		9 wp	11	
SPRAIN	4	8 wp	9 wp	4			4	
STAPHLOCOCCUS	7	8 wp	12 wp			10 wp		11 wp
STREPTOCOCCUS	11	6	9 wp	14 wp		5 wp	9 wp	
TUBERCULOSIS	12	13 wp	4	6	7 wp		10 wp	6
YELLOW FEVER	14	14 wp	10 wp	5			9	10

SUPER PRO RESONATOR
#532



INSTRUCTIONS AND INFORMATION

THE PRESENT PRODUCT LINE OF PULSE GENERATING EQUIPMENT IS DESIGNED AND MANUFACTURED FOR RESEARCH PERSONS FOR INVESTIGATION AND EDUCATIONAL STUDY OF PULSE ENERGY ON PLANTS, ANIMALS, AND HUMANS. THIS TYPE OF EQUIPMENT IS NOT INTENDED FOR THE SPECIFIC TREATMENT OF ANY DISEASE IN ANIMALS AND HUMANS, BUT MAY BE USED FOR THE STUDY OF THE EFFECT OF PULSE STIMULATION. PLEASE NOTE:

NO MEDICAL CLAIMS ARE MADE OR IMPLIED IN THE USE OF THESE DEVICES. FEDERAL LAW PROHIBITS THE USE OF THIS TYPE OF EQUIPMENT FOR THE TREATMENT OF DISEASE

SUPER PRO RESONATOR

RESEARCH : TENS PULSE GENERATING EQUIPMENT

A. OVERVIEW

1. INTRODUCTION

Pulse generating devices are designed and manufactured for educational and investigational study of low and high pulse repetition rates of energy on plants, animals, and humans, but can be used for the study of the effect of pain or stimulation of nerves and muscle tissue, as well as the response to the stimulus. NO MEDICAL CLAIMS ARE MADE OR IMPLIED IN THE USE OF THIS DEVICE.

The output of this device is usually used with conductive pads to apply the energy transcutaneously (through the skin) or by means of magnetic radiated energy. This device is designed and manufactured for the serious researcher interested in results from the use of Pulse Generation equipment. The latest generation of pulse generation devices is the 'SUPER PRO RESONATOR'.

There has been much research and equipment developed and used over the last 60 years since the advent of radio. One researcher, Georges Lakhovsky, a Russian scientist, developed a system in the 1930's using a Tesla Coil to provide energy in the science of 'Radio Biology'. Information on his work can be obtained in his book "The Secret of Life" or Mark Clement's book "The Waves That Heal". The Lakhovsky device the 'Multiple Wave Oscillator', or MWO, used a two state system - on and off - to provide his unique signals.

Also during this period of time, another individual, Raymond Royal Rife was also experimenting with the 'on and off' two state system, to effect the disintegration of the electromagnetic field surrounding certain harmful bacteria, virus and fungus. By 1934, with the aid of several Medical Doctors, he had successfully cured 16 of 16 cases of human cancer - within three months time.

A recent book "The Cancer Cure that Worked - Fifty Years of Suppression" details the heroic efforts of Dr. Rife and his successful work with pulsed generating equipment to destroy specific pathological microorganisms electronically. He knew, like Georges Lakhovsky and many others, that each kind of cell has a specific frequency of interaction with the electromagnetic spectrum, and he believed that an electromagnetic frequency would have a negative effect on bacterial forms.

He developed a microscope which would allow him to see the bacterial form in its natural state. With his microscope, he was able to develop a frequency of light and coordinate the frequency with the chemical constituents of the particle or microorganism under observation. With much research, he was able to identify specific frequencies and cause bacterial forms to die. Unfortunately, with the politics of the time, the medical profession did not support the work of Dr. Rife and his discoveries were mostly forgotten or ignored.

The research on George Lakhovsky, Dr. Rife, and other's discoveries has continued - but not in the public's eye. During the past ten years, scientists, MD's, Chiropractors, Naturepathic Physicians, and others, have been working to better understand the technology of Dr. Rife's (Frequency Generator), Georges Lakhovsky (the MWO), M. Edwards (the Edwards Myo-Flex), G. Hamilton (Gravitic Life Ray Amplifier), in an effort to re-create a device utilizing the novel principles proscribed by these great scientists.

Two years ago, several scientists, including Ed Skilling, were able to locate many of these devices and unravel the science and electronics behind them. Following two years of hard work and testing different models, the TENS SUPER PRO RESONATOR was built by Ed Skilling. This TENS device combines the benefits of the vacuum tube technology and improves the performance of the original devices (they used outdated 1930's technology) with bold solid state dependency.

The SUPER PRO RESONATOR and its forerunner have been used in research clinics for the past 18 months with astounding results - which baffle the most critical skeptics.

Side effects to the TENS device have shown individuals with bacteria, fungus and viral infections report the infection gone after only two to ten non-invasive sessions. Individuals with more serious conditions, have reported improvement in as few as seven and in as many as twenty-five sessions.

Additional research clinics continue to use the device and report new benefits. Medical Doctors, Chiropractors, Naturepathic Physicians, Licensed Therapists are all using this non-invasive device in their research efforts. A typical session runs 25 minutes every day or every other day depending upon the ability of the body to eliminate the toxins (see Operating Instructions: Suggested Protocol).

2. EARLY THEORETICAL ASSUMPTIONS

Historical data indicates that several types of TENS pulse waveforms were believed to have had the ability to destroy bacteria, viruses and fungi. Many theorists, including Rife, believed that each pathogen has a unique size that can be resonated and "blasted" with its exclusive tuning - like a wine glass shatters with a specific tone. But in understanding the phenomena, many of the scientists developed a theory of "Frequency Instrument Therapy". There is much confusion in this area and centers around understanding the differences between pulse repetition rates and the use of frequencies.

Many of the builders of current frequency machines believe that a FIT wave and its theoretical principles are sound. However, research and an understanding of the nature of the signals produced, provide valuable insight into why a 'square wave' frequency generator cannot possibly work by itself.

All FIT waves pulses are electrical, not acoustical, and therefore won't 'vibrate' cells even at critical dipole resonance except for minute piezioelectric effects found only in bone and some cell (not viral) membranes; also FIT wavelengths are many orders of magnitude longer than 1/4 wave resonances of viruses.

Square wave generators, by definition, will produce a square wave containing an infinite number of odd harmonics extending beyond the many Megahertz in transformerless designs. The use of the Square Wave confuses the use of repetition rates with a coherent, discrete cell frequency. This misunderstanding handicapes the field of today's efforts to advance electromedicine and the development of properly working experimental instruments.

Each and every pulse repeating in the SUPER PRO RESONATOR produces thousands of actual, discrete, individually measurable frequencies in the form of harmonics as displayed with frequency-domain spectrum analyzers. Oscilloscopes cannot show these embedded harmonics since scopes show only time-domain displays. The nano-Hz and pico-Hz signals active at viral dimensions cannot possibly penetrate the body because of "skin effect" (Eddycurrent) repulsion, even if they were present, which they are not. Embedded harmonic "frequencies" unrecognized by the FIT theorists are what make a flute, piano, or trumpet although playing the same note (Hz) sound entirely different.

3. CURRENT HEALING HYPOTHESIS

A theoretical hypothesis which may better support the resulting effects generated by the TENS SUPER PRO RESONATOR may be that the body's internal endogenous immune system is activated by the alien electro-magnetic signals and a broad spectrum of neuropeptides, hormones, leukotrienes plus other antibodies are rapidly stimulated into production. This is proven in chromatography which shows that neurotransmitters are produced when TENS (Trancutaneous Electrical Neuro Stimulation), C.E.S., or other electrical treatments are used for pain or stress.

There are over 2,000 peptides identified at present. Some are produced by human skin. Cytokines like Interleuken and Interferon are thought to be immunization factors for a broad spectrum of diseases ranging from the common cold to Cancer. Neurotransmitters like Beta Endorphins alleviate pain. Our body's complex healing interactions appear limitlessness.

4. STATE OF THE ART TECHNOLOGY

Devices currently having the greatest successes and providing the simplest methods of operation are those using pulse generating acoustic signals - like the TENS SUPER PRO RESONATOR. These devices have been under testing and development during the last two years.

The original generating device was provided with a vernier dial and a digital frequency counter used to set the device to precise frequencies. The second generation device was powered with five stable solid state integrated circuit oscillators in which the frequency changes were controlled by a five-position rotary switch on the front panel. The unit contained an electron tube to provide an excellent match to the human body and provided maximum transfer of energy.

The third and present frequency generator uses stable solid state frequency controlled oscillators (both mechanically and electrically), and successfully replaced the vacuum tube technology with reliable, dependent solid state equipment. Ongoing research indicates the solid state out-performs the hybrid solid state/vacuum tube unit generation. Critical adjustments in the frequencies provided have resulted in rapidly recovering situations and elimination of 'certain' previous states from recurring.

B. OPERATING PROCEDURES

The device has been pre-set to afford the investigator with a powerful but easy to use TENS pulse generator. Suggested procedures for the operation of the device are as follows:

1. INTRODUCTION

a. Examine the face of the device. Note, on the left hand side there is a dial with letters from 'O' to 'E' on the box. These are the pre-set frequencies to be used during all experimental sessions. To the center, marked 'OUTPUT', are two receptors: one small and one large. The small receptor is used for connecting the sponge pads, when used; the larger one is used for attaching the two stainless steel applicator plates to the unit.

b. Find the 'GAIN' knob located to the right center and the 'ON' switch located to the far top right. The GAIN switch is turned clockwise (to the right) to increase the signal amplitude, and turned counterclockwise (to the left) to decrease the amplitude. When the 'ON' switch is pushed toward the top (up) of the unit, the device is 'ON'. The green light will shine whenever the unit is plugged into an active outlet and the switch is in the up or 'ON' position.

2. UNIT 'OFF' POSITION

Before using the unit, turn the FREQUENCY dial to the 'O' position - turn the dial all the way to the left; turn the GAIN dial all the way to the left; and push the 'ON' switch down. Now the unit is in the 'OFF' Position.

3. USING THE OUTPUT PADS

Whether the researcher uses the 'OUTPUT' sponge pads or stainless steel applicator plates or both is left to the discretion of the investigator. Current research is inconclusive as to which approach provides greater results. In all applications, applicators should be placed ONLY on the soles of feet, never on other areas of the body (unless otherwise instructed). Both OUTPUT devices may be used but only on one subject at a time. If both OUTPUTs are used by separate subjects, the resulting amplitude will be very weak, session protocals have not been developed, and results are unknown!

To use the OUTPUT devices, some recommended approaches are as follows:

a. Stainless Steel Applicator Plates - Place terry-cloth pads (inexpensive wash-cloths moistened in chlorine free water and/or diluted salt-water) or several layers of soaked paper towels between the bottom of the subject's feet and the two applicator pads. Reynolds heavy-duty aluminum kitchen foil can be used for temporary or expendable applications. The pad metal should NEVER be placed directly on bare skin. You may use the 'Bucket' method by using two plastic buckets containing water and/or add conductive material such as Epsom salt, sodium chloride (table or sea salt), or hydrogen peroxide to the water. Submerge one of the pads in the water, in each of the buckets. Place each foot over the plate surface with the pad of the foot covering the surface. DO NOT use immersion if there are cuts, rash, sores, or abrasions on the feet.

b. Sponge pads - You may use the 'Direct' application or 'Bucket' method:

(1). To use the 'Direct' application method - Use the stainless steel plates and place the feet on the plates or use the bucket method as explained in (3a) above. Take the foam pads, wet the surface of the pads with chlorine free water and/or a conductive solution of sea salt, epsom salt, or plain tap water, and place the pads, foam down on the area to receive the pulses.

(2) To use the 'Bucket' method use two plastic buckets containing water and add conductive material such as Epsom salt or sodium chloride (table or sea salt) to the water. Submerge the pads and place one in the water, in each of the buckets, sponge side up. Place each foot over the sponge surface with the pad of the foot covering the sponge surface. DO NOT use immersion if there are cuts, rash, sores, or abrasions on the feet.

4. OPERATING A SESSION:

a. Make sure all controls are turned to the 'OFF' position (see Item #2 above).

b. Place either the male plug of the sponge pads or the stainless steel applicator plates, NOT BOTH (unless using the 'direct' application method), into the corresponding OUTPUT connection. Prepare the OUTPUT pad/plate for the feet as outlined in (3a) and (3b) above. Turn the POWER switch to the 'ON' position.

c. Turn the FREQUENCY knob to position 'A'. Turn the 'GAIN' knob slowly to the right and STOP when the tingling sensation 'feels' comfortable.

d. Allow the FREQUENCY knob to remain on each setting for a minimum of five minutes. Times may be extended to a maximum of eight minutes per frequency setting with very rigid, aged, or entrenched subjects.

e. At the completion of the five to eight minute interval, turn the FREQUENCY knob to the next setting i.e. 'A' to 'B' and continue to turn the knob to each succeeding setting every five to eight minute interval i.e. 'B' to 'C'; 'C' to 'D'; etc. until the session is completed.

f. When the last setting (i.e., 'E') is finished, turn the GAIN knob to the left - to the 'OFF' position; turn the FREQUENCY knob to the left or 'O'-'OFF' position; and push the POWER switch down to the 'OFF' position.

Clean and replace the pads/plates as required. CAUTION: Do not grab the pads/plates by the cord - this may cause the connections to weaken. Grab the pads/plates by the plastic male plug in the OUTPUT hole and gently remove the plug from its position.

5. SUGGESTED PROTOCOL:

Researchers have suggested each experimentor MUST select their OWN session guideline. Experience has shown that some subjects, who have severe situations, can release greater amounts of toxins than others whose conditions are not as severe. Some subjects are able to handle the release of toxins better than others. This phenomena appears to be related to the subjects severity of the condition; the ability of the immune system to discharge the toxins; the general state of the subjects body tissue; and the eating habits of the subject.

It is very important for the experimentor to use conservative session modalities and to treat each subject as a unique experiment. Dependant upon the ability of the subject to accommodate the release of toxins will be a major determinant in the session protocol and duration chosen.

Some proposed session guidelines are:

a. Repeat the session daily for two consecutive days with the dial setting from 'A' to 'E' - 25 minutes only. Then no sessions for the next three days to allow the body to re-balance and handle toxins. Then twice a week for three weeks. Check results following this session to determine the effectiveness of the session protocol. Adjust as required!

b. Use the device twice a day (once in the morning and once in the evening) for 25 minutes only (5 - 8 minutes each setting) and continue on this schedule if the body is able to handle the toxins.

c. Some researchers augment the sessions with nutritional supplements to assist the body to detoxify and to replace or resupply nutrients lost during the detoxifiction process or as a result of damages suffered from the unhealthy state.

d. Some General guidelines for : (1) *Very severe cases* - one session a week for several weeks and then one session every three days; (2) *Moderate cases* - one session every other day; (3) *Slight problems* - one or two sessions a day: (4) *General maintenance* - once a week or whenever a problem seems to occur, twice a day until problem disappears.

C. SPECIFICATIONS

The unit is housed in a 7" x 7" x 2" molded plastic carrying case with an adjustable handle.

The unit is powered with 110 volts

60 cycle, ordinary household current. The unit produces a 60 volt peak to peak Square Wave with pulsed frequencies.

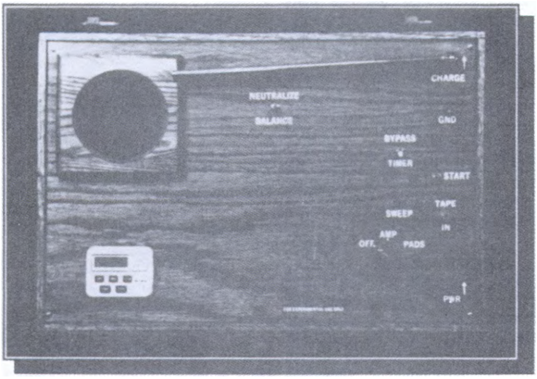
The voltage output to the pads is equal to .02 microvolts - way below the safety standard for output units. The current flowing to the pads is not enough to power a light bulb in a flashlight . The output felt by the user through the pads is the pulsed frequencies generated by the unit - not electrical output.

D. WARRANTY

The Unit is warranted, by the Manufacturer, for a period of one (1), year from DATE OF PURCHASE. The warranty covers defects in material and workmanship. All parts and labor are covered under the warranty.

IMPORTANT: Experience with the SUPERS PRO RESONATOR indicate the need to exercise caution in its use. As with all experimental devices, careful and thoughtful moderation is always the BEST approach!

#526-A SWEEP III

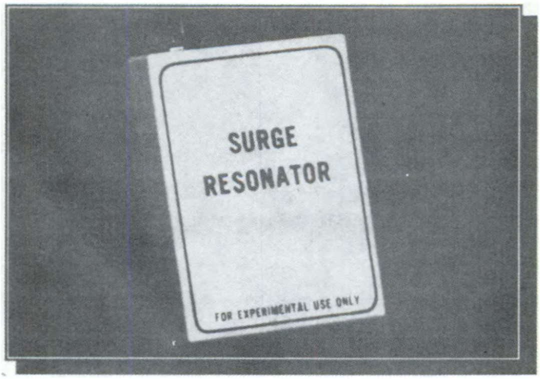

CHARGE
NEUTRALIZE
BALANCE
GND
BYPASS
TIMER
START
TAPE
IN
SWEEP
AMP
OFF
PADS
PWR

The sweep III resonator is completely automatic, including pulse range and modulation. Harmonics of the top range can be found as high as 50 MHz. Input is provided for the analog signals from a cassette player/recorder which is converted to digital signals. This section of the Sweep III can be used to make subliminal output signals at 20,000 Hz, modulated by whatever information is recorded on the tape. A digital timer is provided. The unique input coil can be used to receive subtle energy signals. The unit comes with a nickel-cadmium rechargeable battery pack which provides 12-volt DC operating power.

See our instruction and information catalog for the Sweep III.

FOR EXPERIMENTAL USE ONLY

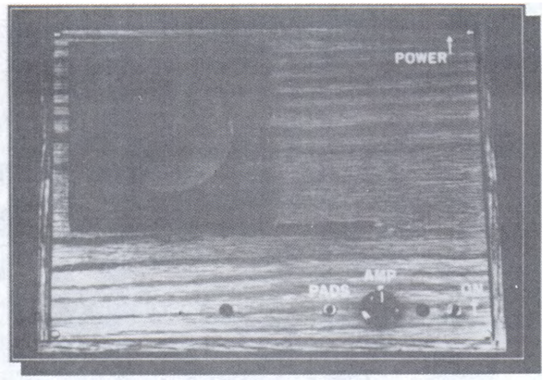
#529-A SURGE RESONATOR



A new experimental pulse generator utilizing a carrier frequency of 100 Hz with a surged low frequency modulation. Tests indicate that this modality produces a subtle energy effect that may balance the etheric body. Quartz crystal timing provides stability. The unit uses a long life 9-volt transistor-type alkaline battery, has a convenient belt clip and a 3.5mm output jack for connection to probes, pads, or other interface devices.

FOR RESEARCH STUDY PROGRAMS
OF VARYING PULSE RATES

#526-B SWEEP IV-B



The Sweep IV-B is a fifth generation sweep generator utilizing the same sweep control used in the Sweep III, fully automatic in operation. The difference between the units is the elimination of the digital timer, antenna, ground lug, battery pack, neutralize balance switch, etc., to reduce the size of the package, resulting in a reduction of cost.

New for '89 is the option to have the Sonofone installed for a small fee. Please call our office regarding this option.

FOR EXPERIMENTAL USE ONLY

#526B SWEEP FOUR-B

THIS UNIT IS THE 4TH GENERATION OF PULSE SWEEP RESONATORS AND IS COMPLETELY AUTOMATIC IN OPERATION. THE UNIT SWEEPS THE PULSE RATES FROM THE LOWEST TO THE HIGHEST EVERY EIGHT SECONDS WITH A REST OF APPROX. 2.5 SECONDS BETWEEN CYCLES. THE MODULATION RATES ARE ALSO AUTO-MATIC IN THAT THEY MODULATE THE ASCENDING HIGH RANGE PULSE RATES FROM 2 HZ. THRU 100 HZ. IN EACH CYCLE. HARMONICS OF THE STEPPED ASCENDING SWEEP RANGE HAVE BEEN OBSERVED AS HIGH AS 50 MEGAHERTZ. THE STEP RAMP SYSTEM ENABLES THE ASCENDING PULSE REPITION RATES TO DWELL FOR SHORT INTERVALS FROM LOW TO HIGH. THE MODULATION RATE FROM 2 HZ. TO 100 HZ. ARE BROUGHT OUT TO THE PADS JACK THROUGH AN AMPLIFIER WHICH AMPLIFIES THE LOW FREQUENCY RATES FOR THE TENS UNIT THRU THE CONDUCTIVE FOAM PADS.

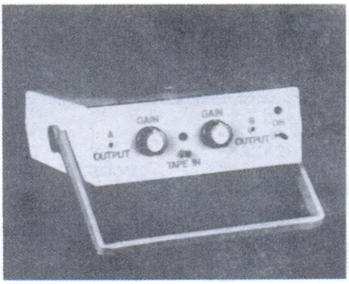
THE HIGH PULSE RATE RANGES ARE BROADCAST THRU THE OUTPUT COILS PRODUCING A MAGNETIC AND ELECTRIC FIELD OUTPUT.

OPERATION

THE AC DC POWER ADAPTER UNIT IS TO BE CONNECTED TO A 115 VOLT AC 60 CYCLE POWER OUTLET. INSERT THE 3.5 MM PLUG ON THE ADAPTER CORD INTO THE JACK HOLE AT THE RIGHT REAR OF THE WOOD CASE, THIS ADAPTER PROVIDES 12 VOLT DC POWER TO OPERATE THE UNIT. PLACE THE POWER SWITCH TO THE "ON" POSITION, THE YELLOW LED TO THE LEFT OF THE SWITCH WILL GLOW, SHOWING THAT YOU HAVE POWER TO THE UNIT. AT THE SAME TIME THE GREEN SWEEP LED WILL ALSO LIGHT INDICATING THE OUTPUT ENERGY IS OPERATING. THE GREEN LED WILL CYCLE ON FOR 8 SECONDS AND OFF FOR 2.5 SECONDS. THE AC 120 VOLT POWER CONSUMPTION IS LESS THAN ONE-HALF A WATT USING THE AC ADAPTER.

TENS FUNCTION

WITH THE MAIN POWER SWITCH IN THE "ON" POSITION, TURN THE AMP DIAL TO THE ON POSITION. CONNECT THE PAD CORD INTO THE JACK MARKED PADS,MOISTEN PADS WITH TAP WATER OR MINERAL WATER TO AVOID THE CHLORINE IN MOST TAP WATER. MOVE THE ROTARY AMP DIAL CLOCKWISE TO INCREASE INTENSITY. ONLY TURN THE INTENSITY DIAL WHILE THE GREEN SWEEP LED IS ON. OUTPUT TO THE PADS THRU THE AMPLIFIER IS ONLY ACTIVE WHEN THE GREEN SWEEP LED IS "ON".



#534 ULTIMATE TENS

NOTICE: The Sweep 3 & 4 and the Ultimate Tens units sweep from 2 hertz to 150,000 hertz. **NOT** 2 hertz to 100 hertz.

THE ULTIMATE TENS UNIT IS THE FIFTH GENERATION OF PULSE SWEEP RESONATORS AND IS COMPLETELY AUTOMATIC IN OPERATION. THE UNIT SWEEPS THE PULSE RATES FROM THE LOWEST TO THE HIGHEST EVERY EIGHT SECONDS WITH A REST OF APPROX. 2.5 SECONDS BETWEEN CYCLES. THE MODULATION RATES ARE ALSO AUTOMATIC IN THAT THEY MODULATE THE ASCENDING HIGH RANGE PULSE RATES. HARMONICS OF THE STEPPED ASCENDING RATE HAVE BEEN ABSERVED AS HIGH AS 50 MEGAHERTZ. THE STEP RAMP SYSTEM ENABLES THE ASCENDING PULSE REPITION RATES TO DWELL FOR SHORT INTERVALS FROM LOW TO HIGH. THE MODULATION RATES ARE BROUGHT OUT TO THE TWO PADS THROUGH AN AMPLIFIER WHICH AMPLIFIES THE LOW FREQUENCY RATES THRU THE CONDUCTIVE PADS.

OPERATION

THE AC-DC POWER ADAPTER UNIT IS TO BE CONNECTED TO A 115 VOLT AC 60 CYCLE POWER OUTLET. INSERT THE 3.5mm PLUG ON THE ADAPTER CORD INTO THE JACK ON THE REAR PANEL OF THE CASE. THIS ADAPTER PROVIDES 12 VOLT DC POWER TO OPERATE THE UNIT. PLACE THE POWER SWITCH TO THE ON POSITION' THE GREEN LED ABOVE THE SWITCH WILL GLOW SHOWING THAT YOU HAVE POWER TO THE UNIT. AT THE SAME TIME THE GREEN SWEEP LED,[BETWEEN THE TWO GAIN CONTROLS,] WILL ALSO LIGHT INDICATING THE OUTPUT ENERGY IS OPERATING. THE GREEN LED WILL CYCLE ON FOR 8 SECONDS AND OFF FOR 2.5 SECONDS. THE 120 VOLT POWER CONSUMPTION IS LESS THAN ONE-HALF WATT USING THE AC-DC ADAPTER.

WITH THE MAIN POWER SWITCH IN THE "ON" POSITION.PLUG THE TWO SETS OF PADS, FURNISHED WITH THE UNIT, INTO THE A & B JACK MARKED OUTPUT. MAKE SURE THAT THE PADS ARE SOAKED IN WATER BEFORE PLUGGING THEM IN. MOVE EITHER GAIN DIAL IN A CLOCKWISE DIRECTION TO INCREASE THE INTENSITY OF BOTH CONTROLS.

PAGE #2

ONLY TURN THE GAIN DIALS WHILE THE GREEN SWEEP LED IS ON, [THE ONE BETWEEN THE TWO GAIN DIALS.] OUTPUT TO THE PADS THRU THE AMPLIFIER IS ONLY ACTIVE WHEN THE GREEN SWEEP LED IS ON.

TAPE PLAY FUNCTION

CONNECT ANY TAPE PLAYER OR RECORD/PLAYER WHICH IS PROVIDED WITH AN EARPHONE JACK, USING THE CORD PROVIDED WITH THE UNIT. THIS CORD HAS AN RCA PLUG ON ONE END AND A 3.5 mm PLUG ON THE OTHER. PLUG THE RCA END INTO THE JACK MARKED TAPE. PLUG THE 3.5 mm INTO THE EARPHONE JACK ON THE TAPE RECORDER. SET THE VOLUME ON THE TAPE PLAYER TWO HALF VOLUME, AND START THE RECORDER TO PLAY. TO CHECK THE UNIT TO MAKE SURE THAT IT IS WORKING, AND BROADCASTING THE MESSAGE THAT YOU PLACE ON THE TAPE, USE A SMALL AM RADIO, AND PLACE THE RADIO ON THE TOP OF THE UNIT, TUNE THE RADIO AROUND 540-600 KHZ ON THE RADIO DIAL. THE MATERIAL THAT IS ON THE TAPE WILL BE HEARD THRU THE RADIO. YOU WILL NOTE THAT IF YOU TURN THE DIAL ON THE RADIO THE SOUND FROM THE TAPE RECORDER CAN BE HEARD ABOUT EVERY 25 KHZ ACROSS THE AM BAND.

WARRANTY

THIS UNIT IS WARRANTED BY THE MANUFACTUE FOR A PERIOD OF (1) ONE YEAR FROM DATE OF PURCHASE. THIS WARRANTY COVERS DEFECTS IN MATERIAL AND WORKMANSHIP. ALL PARTS AND LABOR ARE COVERED UNDER THE WARRANTY.

THE PRESENT PRODUCT LINE OF PULSE GENERATING EQUIPMENT IS DESIGNED AND MANUFACTURED FOR THE RESEARCH PERSON FOR INVESTIGATING AND EDUCATIONAL STUDY OF PULSE ENERGY ON PLANTS, ANIMALS, AND HUMANS. THIS TYPE OF EQUIPMENT IS NOT INTENDED FOR THE SPECIFIC TREATMENT OF ANY DISEASE IN ANIMALS AND HUMANS, BUT MAY BE USED FOR THE STUDY OF THE EFFECTS OF PULSE STIMULATION.

PLEASE NOTE

NO MEDICAL CLAIMS ARE MADE OR IMPLIED IN
THE USE OF THESE DEVICES. FEDERAL LAW
PROHIBITS THE USE OF THIS TYPE OF
EQUIPMENT FOR THE TREATMENT OF DISEASE

AUTO SWEEP RESONATOR

#526A
SWEEP III

INSTRUCTIONS
AND
INFORMATION

THE PRESENT PRODUCT LINE OF PULSE
GENERATING EQUIPMENT IS DESIGNED AND
MANUFACTURED FOR RESEARCH PERSONS FOR
INVESTIGATION AND EDUCATIONAL STUDY OF
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SCIENCE OF THE FUTURE COMING FROM THE PAST

I. BACKGROUND INFORMATION

Everyone has heard of it...The Black Box... That illusive radionics device that people feel too good to be true, but it exists! Now, through higher technology and the understanding of Scalar Waves, it has been improved upon and made simpler to use. Anyone can operate this improved Sweep Resonator because they no longer have to be specially trained.

The first act in the drama of radionics opens with it's first discovery by the great American genius, Albert Abrams in the late 1920's. He went through many trials and tribulations trying to bring his unorthodox device to the public, but it primarily stayed underground. Radionics had not only revitalized the healing arts, but also increased Agricultural Production without fertilizers or harmful pesticides. This in itself proved valid by various experiments and results and therefore threatened the status quo.

Even if you have not heard of Abrams, many of you will remember stories of the mysterious hieronymous box, and many of its uses. Most widely acclaimed was the experiment done on a plot of cotton infested with Boll Weevils and the pesticide that would eradicate the Weevils. When these frequencies of the cotton plot, Boll Weevils, were ascertained, and fed into the box, the plot photographed became totally divested of the Weevils.

With these early devices one would have to trained up to 3 months, and even then, some could not operate the device. Each step taken in which a frequency had to be found was either done by a rate book, usually written by the builder himself, or had to be found by getting "stick". This process involved rubbing a piece of rubber, ebony or plastic until the frequency sort of made ones finger's "stick" or difficult to move across its surface. Many people were not sensitive enough to produce "stick" and, therefore, could not operate the device.

With the Sweep Resonator "stick" is not necessary because it is a multi band resonator that sweeps all frequencies, homing in on the frequencies that are put into the well. The operation now becomes a matter of one, two, three.

Let's say that we want to reproduce the Boll Weevil Experiment:

1) One would gather together a photograph of the field area that is infested, one of the dead insects in a plastic bag, and some of the reagent or pesticide in a small bottle.

2) Place these three items in the well of the Resonator.

3) Turn on the power switch to the Resonator.

At this point, leave it to resonate and sweep for several hours, repeating the process until the desired results are obtained.

The uses are diverse and boundless as your own mind limits you in experimenting with these two models.

The Pro model is also an Auto Digital Sweep Resonator. The pulse range and modulator are fully automatic. This Pro model contains the Tens unit as well, for muscle relaxing effects, or passive exercise. When placed on a muscle it will strengthen, exercise, but relax the muscle, acting as an aid in the relief of pain and stress. You can read, watch TV, or listen to stereo while benefiting from the effects of this muscle relaxer that actually strengthens a muscle when the intensity is used at the highest setting, or at a lower setting, relax and soothe... Aiding pain or the effects of stress. A single output is provided with two conductive flexible foam type pads.

What sets the Pro Model aside is that it contains a Subliminal Broadcaster which can be used in conjunction with the Radionics device. There is an input for audio tape signals or suggestions. Use any subliminal tape that is pre-made or make your own, then simply plug your recorder into the "Pro"; Put the antenna up, put a photograph into the well, and press play on your own recorder. You will hear nothing as the harmonics are of the higher range, and have been measured as high as 50 Mega Hertz. The carrier is modulated by audible frequencies of the voice. An input coil converts input energy to digital pulse output automatically. Your subliminal message is broadcast straight to the brain, and bypasses the auditory or hearing. Positive affirmation are recorded on a cassette tape and the tranducer will broadcast an electric field which is picked up through the subconscious of the individual who may want to receive a positive suggestion.

For instance, ones brain can be programmed into losing weight while watching the evening news or gyrating to Michael Jackson. Send a subliminal message to a friend far away to call you on a Saturday, because you've been "out of touch". There are many subliminal experiments that can be successfully reproduced and thousands you can do yourself! Through the technology of radionics there are no limits to its use for the serious researcher.

Radionics is not only an important new science in its own right; it is also a dramatic reversal of the scientific and technological trends of this age. Modern science has concentrated on developing more and more powerful forms of energy and more and more powerful engines. By contrast, Radionics is the science of Infinitesimal Energies, and of subtle, intangible, but highly potent forces dealing primarily with those fields, known and unknown. Radionics offers almost limitless scope for research, a whole new unexplained continent of knowledge offering unparalleled opportunities for some scientist Columbus or cook of the future... Maybe its YOU!!!

II. GENERAL DEFINITION

Resonance is the reinforcement or intensification of electrical vibrations. As an example, mounted two tuning fork resonators of the same pitch with their open ends facing each other. Strike one with a soft mallet and then quickly clench it by grasping the prongs with one hand. The other fork will be found to be sounding loudly enough to be heard over a large room. They come into sympathetic vibration with one another.

Like the resonance of the tuning forks, all "matter" in the universe is electrical and is vibrating at a specific vibration producing minute oscillating circuits, when an electrical signal is producing an oscillation and this energy strikes a molecule of "matter" that is tuned to the same frequency, it will cause the matter to oscillate in sympathetic vibration.

If the electrical configuration of the "matter" (molecules or atoms) is out of electrical balance and may not be its natural intensity, we believe that the electrical oscillating signal will stimulate it to come into sympathetic vibration and be restored to its equilibrium or resonance.

Pioneers in experimentation with this theory using electrical oscillators such as Dr. Albert Abrams, who may have been the first in 1915, and his protege Dr. Ruth Drown and others that followed such as Georges Lakhovsky, were successful in experimental demonstrations with the principles of electrical resonance.

III. OPERATING INSTRUCTIONS

A. Sweep Resonator

When the master power switch marked 'pwr' is turned to 'on', a red lamp to the left of the switch will glow indicating power is available to operate. If the Timer Bypass switch is in the Timer position, only the sub-carrier signal and other circuits are active except for the Sweep Pulse Generator.

Turn the Timer Bypass switch to Bypass. A green LED lamp, just above the Master Power switch, will pulse indicating the sweep circuit is active. In addition, a green lamp marked 'sweep' will glow at 8 second intervals indicating the pulse rates are sweeping from low to high with a rest duration between cycles.

To time the sweep circuits, flip the switch from Bypass to Timer; set the time on the Timer from 1 minute up to 23 hours 59 seconds. To operate the Timer - press the Timer 'min' button to 1 minute and press the Timer Start button; then press the Red Start button. A green LED, below the Timer Switch will glow bright and then dim indicating the sweep is operating. At the end of the 1 minute test, the timer will beep and the Timer Red Lamp will glow for a moment which indicates end of time. The timer will beep for a full minute unless the Timer Stop button is pressed. To reset, press Stop, then Clear! If the Stop is not pressed, the timer will beep for one full minute and will register (time missed) and count upward until stopped. At any time during a timing cycle, the Stop button will stop the action. To operate the unit without the timer, place the Timer switch to Bypass.

B. Tape Play Function

Connect any tape player or record/player which is provided with an earphone output jack using the cord provided with the sweep unit. This cord uses an RCA plug for the sweep with the opposite end using a 3.5 mm plug for the tape unit. Turn Bypass switch to Timer -turn Master Power on-- start tape player. In this position only the tape output will be broadcast. Set volume of tape player unit at half volume setting. To check material being broadcast-place an AM tuned radio near auto sweep case and tune radio around 540 - 600 KHz of radio dial. The tape material being broadcast will be heard in the radio. You may note that sound can be heard about every 25 KHz across the AM band spectrum. You are hearing a 25th harmonic of a digital clock oscillator modulated by the tape material. Our broadband electro-field detect device will also pick up the broadcast - without using a radio. If the sweep circuit is active during the test, it may be difficult to hear the tape material due to the sweep sound, which can also be heard on its harmonic signal in the radio. This is a normal function.

C. TENS Function

Place Power switch to 'on', use either position of Timer/Bypass switch. If in Timer position, the Red Start button must be pressed to start. Note: The Red Start button will operate the sweep without setting the Timer but will not shut-off automatically unless the timer procedure is followed.

Turn Amp dial to 'on'. Connect pad cord into the pads jack, moisten pads with tap water or mineral water to avoid the chlorine in most tap water. Move rotary Amp dial clockwise to increase intensity. Only turn Intensity dial while the green sweep is lighted. Output to pads through the amplifier is only active when the green lamp is 'on'. To conserve battery power, always leave Amp switch in the 'off' position when pads are not being used. Also, if a timing function is not used, set Timer/Bypass switch to Bypass. The timing circuit also consumes battery power. If the AC to DC power adaptor is connected, battery power will not be consumed. If unit is being broadcast continuously it is advisable to keep the AC adaptor connected.

IV. SPECIFICATIONS

This unit is in a wooden case with overall dimensions of 12 x 18 x 5 inches. The input of the resonator is a free standing basket weave coil. This coil is a part of the input to a clock oscillator and in this case, employs LRC inductance-resistance capacitance. Coils of this type were used in early radios in the 1920's and 1930's now called antique radios. The unique design of this type of coil provides a Hi Q with low interwiring capacitance. This means that it has good ability in 'capture area' for weak subtle signals. These coils have been found to be efficient in the capture of 'radiant energy', a term used by Nicola Tesla in 1905.

The input digital clock oscillator using this coil provides a signal that can be modulated by a second digital sweep clock oscillator that provides a broad band of pulse rates from 1 Hertz to over 50 Mega Hertz in harmonics.

The unit sweeps the pulse rates from the lowest to the highest every eight seconds with a rest of approximately 2.5 seconds between sweep cycles. The modulation rates are also automatic in that they modulate the ascending high range pulse rates from 2 Hz. thru 100 Hz. in each cycle. Harmonics of the stepped ascending sweep range have been observed as high as 50 Mega Hertz. The step ramp system enables the ascending pulse repetition rates to dwell for short intervals from low to high.

The modulation rates from 2 Hz. to 100 Hz. are brought out to the pads jack through an amplifier which amplifies the low frequency rates for Tens Units thru the conductive foam pads. The high pulse rate ranges are broadcast thru the output coils producing a magnetic and electric field output.

A sub-carrier also modulates the output magnetic circuit and is provided with an input for cassette type tape players or recorder/players which can be used to broadcast music or other material to plants and animals.

Between the input coil to the output pancake type coil and antenna, there is a total of 8 integrated type solid state devices to provide a broad band output of digital pulses in a sophisticated system that contain a subtle energy that may not be easy to measure or to be seen.

The auto sweep resonator is provided with conductive foam pads that can be used in the same manner as a TENS pulse generator. A clock timer is provided to limit the duration of use of the sweep. An input jack marked 'tape' is used to accommodate the output of a tape player or recorder.

For power, a nickel-cadmium battery pack provides 12 volt DC power to the circuits. An AC to DC converter is also provided to recharge the battery pack. The built-in output coil with antenna provides the electric and broad band field. There are no dials to set; the unit is completely automatic. An on/off switch and timer turns the power 'on' or 'off' to conserve power. When a timing function is not needed, a timer Bypass switch is provided. The AC 120 volt power consumption is less than one-half a watt using the AC adaptor.

D. WARRANTY

The Unit is warranted, by the Manufacturer, for a period of one (1), year from DATE OF PURCHASE. The warranty covers defects in material and workmanship. All parts and labor are covered under the warranty.

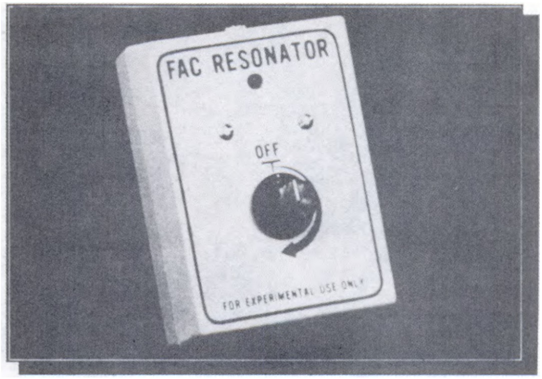
#504 LIL-RESONATOR

LIL-RESONATOR
FREQUENCY
OFF
FOR EXPERIMENTAL USE ONLY

A low cost unit with two control dials, rate and intensity, and improved linearity. A new high-impact plastic case features a battery compartment with sliding door on the rear of the unit, for ease of access. 1 Hz to 65 Hz frequency range, with a calibration mark on the dial at 7.83 (the Schuman earth resonance pulse rate). Single output through a 3.5mm mini plug for use of probes, pads, or other interface devices. Lil-Resonator comes complete with battery, instructions, and one set of flexible foam pads.

FOR RESEARCH STUDY PROGRAMS
OF VARYING PULSE RATES

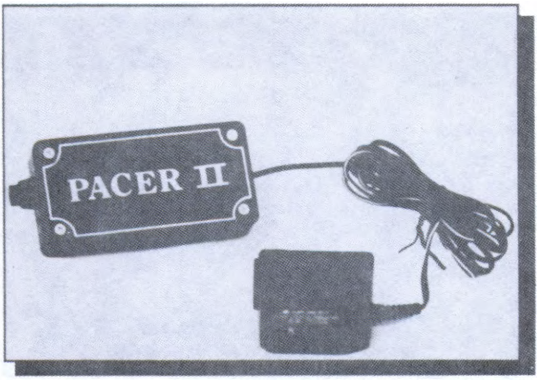
#507 FAC RESONATOR


FAC RESONATOR
OFF
FOR EXPERIMENTAL USE ONLY

This low frequency pulse rate generator is designed to be used by researchers in the study of the effects of magnetic phosphene in its relation to balancing the etheric field of the human or animal aura. Easy to use, with instructions included.

FOR RESEARCH STUDY PROGRAMS
OF VARYING PULSE RATES

#511-A PACER II



The design of the Pacer II is based on the theory of Dr. Ludwig of Germany that a magnetic field at the ELF Schuman earth frequency (7.83 Hz) may be beneficial in providing a shield against the influences of manmade electromagnetic fields such as are produced by computers, television, and other electronic devices that surround us in today's high technology world. Pacer II has increased pulse rate stability and digital pulse output with less magnetic power but increased effect. This unit has an AC-to-DC adapter so it can be operated 24 hours per day, eliminating the need for a battery. It radiates a field within a 2 to 3 foot radius which surrounds the user with a protective shield.

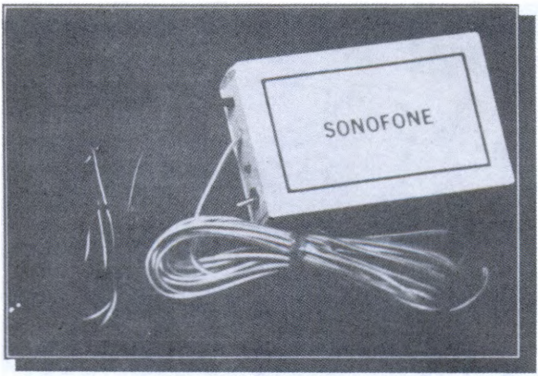
FOR EXPERIMENTAL USE ONLY

#511-B PACER III

The mini Pacer III uses the same electronic circuit that is in the Pacer II, but reduced in size to allow for easier carrying in a pocket or purse. It is in a new miniature plastic case, has a convenient belt clip, and uses a long-life 9-volt battery. The Pacer II provides the same protection from electromagnetic "smog" as the previous Pacer units.

FOR EXPERIMENTAL USE ONLY

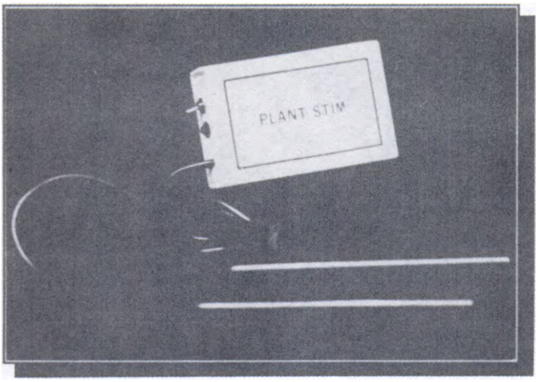
#523 SONOFONE



This experimental device is designed for the researcher in subliminal learning processes. It utilizes a carrier frequency just above the average hearing level of 20,000 Hertz, modulated by audible voice frequencies. Make your own subliminal tape message using your tape recorder or player. For example, record your own positive affirmations on a cassette tape, then it play back using the Sonofone. The transducer broadcasts an electrical field picked up by the subconscious of the listening individual. No consciously audible sound is heard when the unit is operating. Play the cassette tape through the Sonofone while reading, watching television, or otherwise relaxing.

FOR EXPERIMENTAL USE ONLY

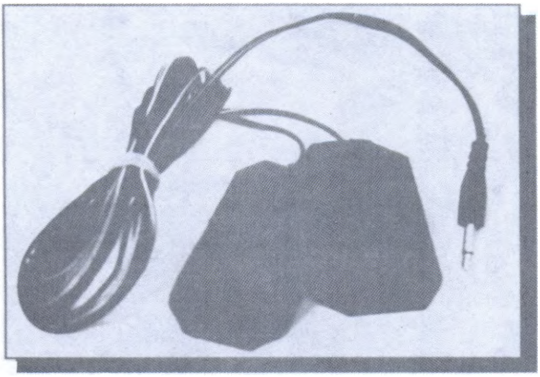
#524 PLANT STIM



The Plant Stim is an experimental device used to stimulate plant growth by inserting two probes into the soil in which the plant grows. Very small pulses operating at the earth Schuman resonance of 7.83 Hz will stimulate the plant to increase the growth rate. In many cases it will revive a dying plant.

FOR EXPERIMENTAL USE ONLY

REPLACEMENT PADS



#506 – $1^1/2$" x $2^1/2$"
Standard Replacement Pads

#506A – $2^1/2$" x $2^1/2$"
Pro Replacement Pads

#506B – 5" x 5"
Super Pro Replacement Pads

TERMS AND CONDITIONS

EFFECTIVE 1-1-89

WARRANTY

If the Purchaser is not satisfied with the performance or quality of any of our products within the first thirty (30) days, Purchaser is allowed to return the item for a refund if the product is in like-new condition. *A minimum 10% fee will be charged if the product is **not** in like-new condition.* **This warranty does not apply to products #526-A and #524-B, or items not listed in our current catalog.**

All of our products have a full one year warranty. If any service is required, please contact our sales department for a return number and shipping address prior to shipping the item back for repairs. Return the item as instructed, prepaid, and we will, at our option, either repair or replace it.

If your order is damaged in shipment, contact the carrier at once. We are not responsible for products damaged or lost by the carrier.

ORDERS FROM OUTSIDE THE UNITED STATES

We are happy to sell to customers in foreign countries. Remember, however, that you have to pay customs and import fees at your end.

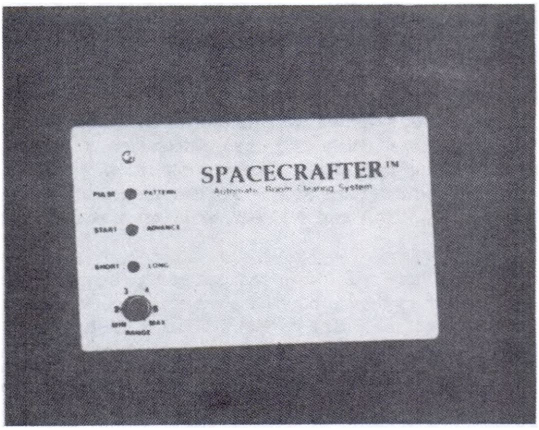
PRICES

E. F. Skilling Inc. reserves the right to change prices without notice, to make changes and improvements in the products, or discontinue items at any time without obligation to make those changes to existing products.

SPECIAL ORDERS

TERMS: Payment in full with all special orders. Allow six to eight weeks (or more) for delivery depending on the time of the year and our work load at the time of the order. Add $4.50 to the order for shipping and handling charges. **ALL SALES ARE FINAL ON SPECIAL ORDERS; NO REFUNDS OR EXCHANGES ARE ALLOWED.** ***THERE WILL BE NO EXCEPTIONS TO THIS POLICY UNDER ANY CIRCUMSTANCES.***

SPACECRAFTER™



SUGGESTED USES

The following is a partial list of possible places or situations where clearing with a Spacecrafter™ may be useful and beneficial.

1) Doctors offices, waiting rooms, examination rooms, bathrooms, X-ray rooms.
2) Chiropractic offices, waiting rooms, exam rooms, X-ray rooms, etc.
3) All rooms used by acupuncturists, massage therapists, psychologists, psychiatrists, counselors, attorneys, groups, trainings, classes, gatherings, seminars.
4) Hospitals, offices, rooms, hallways, operating rooms, X-ray facilities, cafeterias
5) Hotels, rooms, hallways, meeting rooms
6) Your home, living room, bedrooms, bathrooms, garage, kitchen
7) Restaurants, seating areas, kitchens, bathrooms
8) Stores, shops, work places, factories
9) Cars, trucks, boats, planes, buses
10) Crystal dealers, stores, stock rooms, show rooms

SPECIAL ATTENTION SHOULD BE GIVEN TO AREAS WHERE X-RAY EQUIPMENT IS USED. This includes areas where X-ray equipment has been removed and where radio-active materials are being or have been stored. These areas need deep clearing using the PATTERN antenna, LONG cycle and numerous settings on the range dial. These areas will produce some of the most dramatic results.

UNDERSTANDING YOUR SPACECRAFTER™

The theoretical basis for the operation of the SPACECRAFTER™ begins in Orgonomic Functionalism as developed by Dr. Wilhelm Reich and proceeds to modern psychotronic circuit behavior discoveries. While this sounds complicated, it can be de-mystified as follows.

Life is a process that animates complex groups of elements, such as your body. Life is characterized by movement, like your heart beat, breath or brainwave pattern. Where there is spontaneous movement, there is life.

Wilhelm Reich discovered that this basic life process exists, not only inside of our bodies, but outside in the general environment as well. The sky, the air and the planet also have a pulse. This evironmental rhythmic movement manifests itself in a number of ways. One of these ways is the subtle variation in the earth's magnetic field, now known as the Schuman Resonance. This environmental signal centers at about 7.83 cycles per second and varies plus or minus one half cycle per second depending on moon phase and sun spot activity.

Wilhelm Reich discovered that there are a number of important rhythmic behaviors in the environmental life energy field. Each one of these behaviors has a specific pattern to it, just like the different patterns present in our breath and pulse. Dr. Reich also found that these basic patterns of behavior can become inhibited, so that the sky could become frustrated or sick just like humans can. The increased simultaneous appearance of droughts and floods worldwide may be graphic proof that the life energy field enshrouding the earth is not at ease. While the SPACECRAFTER™ is not capable of normalizing global weather conditions, it is capable of easing the tensions in the life energy field in enclosed evironments.

A room can feel strange or promote a certain mood because the life energy field in that room is not as free to pulse at some frequencies as easily as it does at others. This can cause subtle distortions in a person's normal brainwave profile and promote a mood that reflects the life enrgy field pulse inhibition pattern of that room. Proper use of the SPACECRAFTER™ can eliminate this effect. In operation, the SPACECRAFTER™ produces a sequence of pulses that starts just below 30 pulses per second and ramps down over its run cycle to just below 1 pulse per second. This helps free the life energy field to behave normally within this range. Because this is the same range as normal human brainwave activity, it allows the life energy field to support any brainwave profile without promoting any mood in particular. By varying the intensity of the pulses and the circuit through which these pulses are applied, the life energy field may be reconditioned to function in its natual, uninhibited state. This leaves the treated area feeling easy and pleasant to be in.

The mass production of a device that reliably creates these effects is not simple. The electronic components which make up the active elements of the antenna systems are chosen, not only for their circuit values, but also for their chemical composition and specific psychotronic action. The SPACECRAFTER™, as a project, took 14 years to develope and constitutes a major breakthrough for commercially available devices. Its unique ability to eliminate unwanted subliminal irritations from indoor environments make it a valuable addition to a health oriented lifestyle.

THE REAPER

Vol. 13, No. 28

July 20, 1989

COSMOS

PUT ON A HAPPY FACE AND A TRUSTING HEART

PART 2

ELECTROMAGNETIC HEALTH

When we realize that the Kaznacheyev experiments in the Soviet Union prove that any cellular death or disease pattern can be induced in cells electromagnetically, it becomes increasingly crucial that we control what we think, believe, and eat, and thereby support our immune systems. The Kaznacheyev experiments have been duplicated in West Germany at the University of Marburg and in Australia at the University of Sidney. In Sidney, this experiment was accomplished at 100 meters distance.

Imagine what the Soviets are doing in this area of psychic/electromagnetic warfare. Psychic warfare is nothing more than a scientific radionic application of what religiously is called voodoo. The Soviets used the 5-28 MHz Woodpecker signal to upset people in Salem, Oregon in 1978. The 1987 Dr. Robert Eastlund and Atlantic Richfield Oil weather engineering patent is along these lines, a phased-array over-the-horizon radar. Shades of Tesla and Tom Bearden.

In 1984, the U.S. Navy demonstrated that ELF (Extra Low Frequency) waves could alter cell behavior, body tissues, organs, hormone levels, cell chemistry, reaction time, inhibit or enhance bone growth, alter cell differentiation, RNA synthesis, DNA transcription, entrain brain waves, slow aging, cure certain diseases, alter time perception, affect the immune process, increase fetus mortality, cause sterility, produce non-invasive genetic engineering and trigger defects and alterations in embryos. And, of course, on a much cruder level, high power lines have been shown to cause cancer and decreased immune response (Denver).

But, there's a positive side to this whole electromagnetic nature of thoughts and wavelengths. The Antoine Priore machine in France in the 1960s and 1970s proved conclusively that electromagnetics can be used to cure diseases such as cancer, leukemia, sleeping sicknesses, and also to positively boost the immune system. It has to do with charging an organ electromagnetically at its healthy resonant frequency. Antoin Priore was initially championed by the prestigious French Academy of Sciences. Skilling and Rapsomanikis have achieved similar results in this country recently. They have been persecuted and harassed, too. But so too were their predecessors - Dr. Albert Abrams and Lakhovsky.

This is along the same line as the work performed by Dr. Royal Rife in the '40s and '50s in this country. Using his Rife microscope, Dr. Royal Rife proved that living entities are composed of structured electricity. These electromagnetic bugs, literally living electricity, which are at work in and around viruses and bacteria, can be killed by methods similar to scalar electromagnetic energy, using color and frequency. This is further confirmation of Darius Dinshah's work with color healing, performed with Dr. Kate Baldwin, chief of surgery for 20 years at Women's Hospital in Philadelphia. Rife was so successful at treating cancer and other maladies that the AMA came in and shut him down. Rife even got thrown in jail. Which reminds me, the very best and the very worst of men are in prison these days. The U.S. rates right up there along side the Soviet Union and South Africa in the percentage of its people it throws in jail, political prisoners. Birds of a feather... (For more reading I recommend The Royal R. Rife Report, available from Borderland Sciences, P.O. Box 429, Garberville, CA 95440-0429.)

The April, 1986 Discover magazine featured the work of Swedish radiologist Bjorn Nordenstrom. Dr. Nordenstrom established the equivalent of electric circuits in the human body. He successfully treated both lung and breast cancer electrically. "*The biological circuits are driven by the accumulated charges,...which oscillate between positive and negative. The larger vessels act as insulated cables, blood plasma as the conductor. In the permeable tissue, the fluid between cells conducts ions. A key component of the circuit: the natural electrodes in the capillary walls.*"

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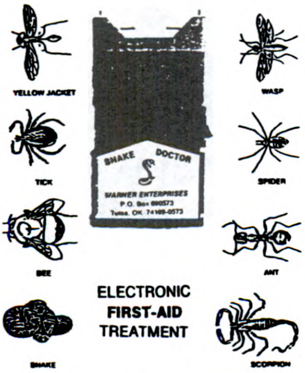
The Reaper,7/20/89 — P.2

Warner Enterprises (P.O. Box 690573, Tulsa, OK 74169-0573, Tel. 918-663-3832) manufactures a device called the "Snake Doctor". The "Snake Doctor" emits 25,000 volts of DC at less than 1 Ma. When applied to snake, spider, ant or tick bites, or wasp, scorpion or bee stings, it allegedly neutralizes the venom. The "Snake Doctor" has been written up in the medical journal Lancet, by Dr. Lawrence K. Alterman in The New York Times, and by research teams in West Germany and at Michigan State University. The electrical current supposedly rearranges the venom's molecular structure into a non-lethal substance.

SNAKE DOCTOR

MANUFACTURED SOLELY TO APPLY
THE ELECTRONIC TREATMENT FOR
POISONOUS INSECT AND SNAKE BITES



ELECTRONIC
FIRST-AID
TREATMENT

MARKETED BY: *WARNER ENTERPRISES,*
P.O. Box 690573, Tulsa, OK 74169-0573
(918) 663-3832

The reality of electromagnetic medicine should really come as no surprise. The earth is a big electromagnet. The ionosphere is electrical. We bounce radio waves off of it. If we oscillate the ionosphere at 8 times per second, we can release usable energy from it (Source: Omni). The magnetosphere and its Van Allen belts produce many kinds of electromagnetic radiation. The earth is a big magnet with a north and south pole. The earth, a magnet, rotates within the ionosphere's electrical field. Plus, we are bombarded by solar charged electromagnetic particles emitted by the sun. Bingo: Electromagnetic reality! The magnetic field of the sun is 8 Hertz. The harmonics are that the human body operates at .08 millivolts and healers heal at 8 Hertz and the earth oscillates at 8 (7.83) Hertz. Dr. Bernard J. Eastland holds patent #4,686,605 whereby artificial lightning can be generated. Given all this evidence, why does the United States allow 10,000 times more electromagnetic pollution than the Soviet Union or Western Europe?

(For more reading see Richard Gerber, M.D.'s book, VIBRATIONAL MEDICINE, John Evans' book, MIND, BODY & ELECTROMAGNETISM, THE DARK SIDE OF THE BRAIN by Harry Oldfield and Roger Coghill, THE BODY ELECTRIC by Robert O. Becker, M.D. and BIOCIRCUITS by Leslie Patten.)

Simple kinesiology (muscle testing) has become a lot more sophisticated. Touch for Health, point holding, chelation, healing with magnets and crystals, the Accupath 1000, the Super Pro Resonator, the Interro. What's next?

The essence of man's spirit (mind field) is electromagnetic. This is what man's electromagnetic field/countenance/aura is all about, as proven by Heisenberg, Abrams, Eccles, Beck, McKenna, Ludwig, Pribrem, Bohm, Talbot, Kirlian, Voll and others. Research at UCLA (Hunt) has confirmed that if you remove the electrical portion of the electromagnetic spectrum from people, they become sad and weep; if it is increased, subjects become joyful and experience mystical spiritual phenomenon. If the magnetic end of the electromagnetic spectrum is removed from an individual, he loses muscular coordination; if it is increased, physical coordination increases (proven with football teams). The electromagnetic spectrum harmonizes with the color spectrum, with violet on one end (electrical) and red on the other (magnetic). Medical instruments measure both electrical and magnetic signals around the head with an EEG and an EMG, respectively. Physicist Gottfried Mayer-Kress of Los Alamos National Laboratory's Center for Nonlinear Studies has worked with the EEG as people shift behavior. He has developed a mathematical model showing how changes in patterns of electrical activity in the brain are linked to changes in behavioral state.

Dr. Phil Callahan, working at Gainesville, Florida and with the USDA has proven that the healthiest of food has an electromagnetic charge, the electrical charge coming from the inorganic mineralization of the paramagnetic rock structure of the soil, the magnetic segment arising from the organic content of the soil which feeds the food-producing plant.

Dr. Jonathan Tennebaum, director of the Fusion

Energy Forum of West Germany, declared in a speech, "*We have abundant evidence that the biosphere is organized as an electromagnetic system in which various processes are very precisely 'tuned' to each other.*" Question: If we are "tuned" to each other, then shouldn't our efforts be cooperative and gentle rather than hostile and destructive?

Wesley Rogers, president of Electronic Development, Inc., has demonstrated that ham radios in automobiles can sterilize men because of improper grounding. Dr. William Adey, a cancer researcher, has proven that cells whisper together in a private and very faint language, and that a block in these signals created by electromagnetic smog can produce tumors and undermine the body's disease-fighting ability. Dr. Robert Becker, author of the important book, THE BODY ELECTRIC, and a research director in a firm which specializes in biomagnetics, declares that the pineal gland, the gland which controls the release of certain brain chemicals, is confused by abnormal magnetic fields, leading to chronic stress and aberrant behavior. So, for good or evil, the present-day equivalent of the French Death Whistle, which the French used against the Germans in World War II to explode their organs internally, is with us. So far, evil rather than good has been the primary direction taken by the Establishment in this area.

INNER WORKINGS

People have to first live within themselves. Literally, the kingdom of God is within and patterned without. Dr. Edmound Burgler, M.D. declared, "*Change of scene has no effect upon unconscious conflicts.*" Environmental determinism does not cut it. Indeed, methods of healing now being taught in seminars at Stanford work with discovering a person's psychological conflict in order to produce the physical healing response. Physical posture can bring to mind negatively handled emotions and violation of God's law which are stored (and are potentially disease-producing) in the body's muscles, organs, bones and other tissues. A teaching nurse informed me that the skill of "laying on of hands" is regularly taught now nationwide.

The conscious mind operates at its own level and talks to itself to try to find answers. But the conscious mind has a limited amount of memory and creative circuitry, because it deals with everyday issues, not deeper issues. Therefore, introspection on the conscious level does not always work. However, when one learns to relax, listen to music or stand still and know God (meditate), one literally enters the alpha state and then is in touch with the unconscious mind and creativity, according to Alan Rogers of Mind Corporation. This is where intuition, hunches and gut feelings come from.

The alpha brain frequency is ten cycles per second. When the brain reaches this frequency level and is also conscious, individuals literally have the ability to program their brain or other consciousness and then to achieve many goals on the conscious level. The human mind normally oscillates between 13 and 30 Hertz. (I might also again mention that all healers measured worldwide with sophisticated equipment operate at 7.83 Hertz, the oscillating rate of the earth, when they are in their healing mode.)

Researchers are using the same radio waves which broadcast the Golden Oldies on the AM dial to treat patients with uncontrolled rapid heartbeats, according to Dr. Jonathan Lamberg of the University of California, San Francisco.

If you want to get really way out, as in the movie "Ghost Busters", use geiger counters and infrared film to locate ghosts/spirits/demons. Such evil spirits only have access to man through defects in the electromagnetic countenance/aura, which in turn reflects unhealthy organs in the twelve primary frequencies of the color spectrum. Incorrect mental and emotional processing (error/sin) plus genetic defects (the sins of the father are visited upon the sons in the chemical make-up of RNA/DNA) cause the defect. Resistance results and impedes energy flow as biological thought crystals are established in the human body (reflexology, for example). This weakness is reflected in the countenance.

If both parents are fat, an individual's chances of becoming fat are about 80%. If neither parent is fat, the chances of an individual becoming fat are only 10%, according to Kenneth E. Warner, M.D., chief medical examiner of the State of Alabama, and Dr. Dale M. Atrans in their book, DON'T DIET. The sins (mistakes) of the father (and mother) are visited upon the sons and daughters through the RNA/DNA structure.

Robert Burton, in his book, THE ANATOMY OF MELANCHOLY, demonstrated that idleness is deathly. We know this from watching career military officers who have been active all of their lives, who then retire. Many quickly die within two or three years, particularly if they become sedentary and depressed. In order to be healthy, people need to do work they love, to work hard, to sweat physically, to eat right, sleep right, think right, and be actively involved with other people. Hypochondriacs are classically people who believe they are relatively powerless, such as children with an overprotective mother, an insecure wife, an unimportant steel worker, or a typical American today at the mercy of the federal government.

Susan Baur, author of HYPOCHONDRIA: WILLFUL IMAGINATIONS, demonstrated that people can literally worry themselves sick, particularly if they are preoccupied with every little ache and pain and view it as a harbinger of some oncoming fatal disease. As a man thinketh so he is. Put on a happy face and a trusting heart.

Caution: Do not initiate any change in lifestyle, diet, exercise or medical treatment without first consulting your physician and/or counselor.

End Part 2

The Frequency Generator Story

The history of the Rife Frequency Generator goes back in time to the 1930's. This era was interesting for the technically inclined person; radio had "arrived" in every sense of the word. Hugo Gernsback was publishing *Radio Craft*, which was full of great information for the do-it-yourself guys and gals who wanted to build radios. In addition to circuits of long and short wave radios, the publication included the subject of short waves in medicine; also, articles on short wave apparatus producing artificial fevers in the human body.

Active during these early years of radio were experimenters such as Georges Lakhovsky, Royal Raymond Rife, and many others. In this paper we will confine our information to the work of a genius, Royal Raymond Rife, and the Rife Virus Microscope Institute. (Note: the following information is taken from a manual written by John F. Crane (1960), loaned to us by Tom Brown, director of the BSRF. The manual was given to Riley Crabb by Dr. Leonard Chapman, frequent contributor to the BSRF before he passed on many years ago.)

Rife developed five powerful optical microscopes, the most powerful of which is known as the Universal Microscope. It was developed in 1933, consists of 5,682 parts, and is so-called "powerful" because of its ability to view accurately microorganisms in their natural habitat. Rife, while observing bacteria, viruses, and fungi when using the microscope, was able to observe their demise while applying energy of the frequency of the square wave generator. Audio frequency generators of the 1930 era were large and bulky, and subject to frequent instability. As a boy scientist of the 1930's, I recall that instrumentation was crude and unstable. To determine the precise frequency with accuracy was difficult and quartz crystal control was required if one wanted frequency stability. It is no wonder that Rife did not publish the frequencies that caused the demise of the viruses that he observed. It would have been difficult for a person other than an expert radio technician or engineer to determine and measure the frequency accurately in 1930.

In the John Crane *Manual* there is no mention of the frequency, only dial settings, which depend upon how the parameters were set up in the oscillator stage. The *Manual* also points out many DO NOT's, which indicates mechanical instability of the instrument. The 1987-88 version of the original Frequency Generator has been developed through a need for an experimental program to investigate and study the work of Rife and perhaps revalidate his experiments using an audio-frequency square wave generator to destroy harmful bacteria, viruses and fungi.

The following information is presented to bring to light the result of a ten-year experimental program using a second-generation Rife Device by an associate in San Diego, California. *Please note that in this story the names of the people involved in the program are not the real names of the individuals.*

In the year 1977, Ingrid von Steinhofer discovered Milton Grosspappa, of San Diego, California, who many years ago knew Rife personally and had asked Rife to help him with a relative who had liver cancer. Rife (not John Crane) provided a Frequency Generator to use in this case. Milton, as directed by Rife, used the Generator and cured the cancer.

Ten years ago, Ingrid had a problem with a relative who had breast cancer. She contacted Milton, who loaned the old Generator to Ingrid — who desired to make a copy of the device for use by a number of people who had various forms of cancer. Ingrid contacted an engineer to duplicate the old Generator. Ingrid always enters a project in a grand manner, so it was decided to make several second generation devices so that they could be loaned to several people at the same time. Ingrid finally received two units, which cost her $10,000. Why the engineer never produced more of the devices for that amount of money is not known.

The engineer, using the number settings of the old generator with an oscilloscope, converted the numbers on the dial settings to actual audio frequencies. We must assume that the numbers on the old dial were correct, as the results of its use in the past ten years indicate. If the numbers were incorrect and the frequencies therefore are not the same as Rife originally developed, then we must assume that the frequencies need not be precise and it may be that all this precision business is not necessary.

Over the past ten years the generators were used numerous times very successfully. Also, Ingrid loaned the devices to a medical technician for use in two clinics in Mexico. The clinics used the units with the same type of success. Use of these electronic devices in the Mexican clinics caused such a financial loss in the sale of pharmaceuticals that the units were removed from service and returned to Ingrid. Ingrid has always provided the devices at no cost to the user.

About five years ago Ingrid met Ed Skilling in Escondido, California. Ed was involved in the development of a neuro-muscular stimulator for use in the medical industry. Ingrid, Ed, and others, went on to form Sontec, Inc., to develop electronic equipment. Several times Ed made minor repairs to the Rife unit and over time learned the history of Ingrid's involvement in the use of the Rife Generator.

In the Fall of 1987, Ed attended a meeting in Los Angeles, California, with a group of medical people and scientists to discuss the possible use of electronics in the treatment of AIDS. A few doctors believe the Rife Frequency Generator may be helpful in the treatment of AIDS. At this meeting Ed volunteered to replicate Ingrid's second-generation unit and create a third-generation device with improvements to simplify usage, particularly in setting the five frequency changes. The second generation unit was provided with a vernier dial and a digital frequency counter was used to set the precise frequencies as called out in the original specifications.

The present, third-generation, device is provided with five stable solid state integrated circuit oscillators in which the frequency changes are controlled by a five-position rotary switch on the front panel. The critical electron tube output stage is the same as used in Ingrid's second-generation Rife unit. Ed discovered a few years ago that the output impedance of the electron tube provides an excellent match to the human body and allows maximum transfer of energy — which a solid state output amplifier will not provide.

The Frequency Generator that belonged to Dr. Chapman, and now belongs to the BSRF group, uses the same type of circuit as the second generation device, except for the tube number. The original Crane unit used a 6V6 octal base. Ingrid's unit uses a 6AQ5, which is a miniature 7-pin version with similar specifications. Ingrid's second-generation unit uses direct DC output. Medical scientists who have studied the reaction of DC electrical energy at the cell level indicate that DC is bad (in spite of the fact that a good many acupuncture devices use DC for stimulation effectively). Ingrid's unit, using a capacitor to block the DC current from the output, and only allowing the alternating square wave current to pass to the output, would be a safer unit to use for the experimental program.

The "1987" third-generation Rife-type frequency generator, with stable solid state frequency-controlled oscillators (both mechanically and electrically), with the ease of shifting the five frequencies using a simple five-position rotary dial, and using the electron tube with cathode follower circuit for maximum transfer of output energy, should prove to be a superior device for the research program.

At this point, December, 1987, it is ironic that the medical doctors who attended the Los Angeles meeting to explore means of treating AIDS electronically have not responded when informed that a Rife Frequency Generator was available for use in their clinics on the AIDS program. The unit that was available for the Los Angeles program is now in a clinic in Mexico.

(More information is available in the book *The Cancer Cure that Worked! Fifty Years of Suppression* by Barry Lynes with John Crane; published in Canada by Marcus Books, 75 Tidefall Drive, Toronto, Canada M1W1J1, (416) 494-6771 or 492-2431.)

During the past ten years that Ingrid's device has been loaned to individuals to treat themselves, and has corrected the problems of disease, it is interesting to note that all applications of the output energy of the Frequency Generator have been by means of two 4 x 8-inch rectangular stainless steel plates. The subject places his/her bare feet on the plates and each frequency is applied for a period of five minutes. This process constitutes a full treatment, once per day. *In every case*, the subject reports a feeling of "well-being" after each treatment. No deleterious reports were ever made. *In every case the device was used by the individuals to treat themselves.*

The device that Milton loaned Ingrid to replicate to the second-generation unit could not have been the same type of unit as described in the manual that came with Dr. Chapman's unit. The "original" unit loaned to Ingrid by Milton referred to *dial settings* — all 5 numbers below 100. The second-generation unit still has the original dial numbers opposite the audio frequencies on the front panel (all below 100) which indicates that the original unit had a large dial with numbers from 0 to 100. A drawing in the Crane (Chapman) *Manual* shows a 0 to 100 dial and a model reference SQ2. The device that Tom Brown has in his museum in California is an SQ1, as is evident from the front panel. This SQ1 Model is certainly not an off-the-shelf standard square wave generator. It is clearly a ***modified off-the-shelf generator***. In its present condition, although it still operates, the frequency and signal output is unstable and unusable. It is not known if the SQ1 was modified by Chapman or some other technician, or if Chapman received it from Crane modified into the present configuration.

NOTES ON EXPERIMENTAL USE OF THE RIFE FREQUENCY GENERATOR

Economic reality dictates that the Rife Frequency Generator can never be officially acknowledged for what it is. It is too inexpensive, too easy to build — and too effective. Anyone who makes use of or builds one of these experimental instruments must be aware of the economic facts of life and what to expect when the establishment becomes aware of the potential impact of this unit.

Acknowledgment and acceptance of the Rife Generator could conceivably destroy 80 to 90% of the following businesses and professions:

Allopathic medicine: Doctors, surgeons, specialists who are among the highest paid professionals in the world — and have invested thousands of dollars and years of training in their fields.
Plastic surgeons: especially reconstruction after medical surgery
Medical researchers and medical research facilities
Universities that have medical schools and research departments
Hospitals
Pharmacists and Pharmacies
Nurses, pathologists, and lab technicians
Medical equipment manufacturers and companies who supply parts to these manufacturers
Pharmaceutical companies: both prescription and over-the-counter drugs, and ingredients used in cosmetic treatments
Optometrists and other eye specialists
Manufacturers of medical appliances such as hearing aids, contact lenses, and eyeglasses
Companies that produce components or ingredients used in any of these medically-related fields
Non-medical personnel employed by doctors, hospitals, pharmacies, medical research facilities, laboratories, etc.
Employees of companies that produce medically oriented products or ingredients
Health maintenance organizations and health insurance companies

Life insurance companies — the largest dollar industry in the world — which invests funds in these industries

Investment companies, institutional investors, pension funds, and shareholders in any of the above listed areas

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Anything having a profoundly negative effect on such a large segment (perhaps one third) of the economy *cannot* **be allowed to exist.** It would cause total economic collapse — worldwide. Therefore, we can expect — based on historical experience — something like the following scenario to occur.

When the establishment becomes aware of the widespread availability of this unit and its potential, a concerted effort will be made to discredit it and discourage people from trying it. We can expect a media blitz on the news, talk shows, and programs like *60 Minutes or 20-20* with "interviews" of people who *supposedly* have used the authentic Rife Frequency Generators and experienced no beneficial effect — or even harmful effects — from them. Doctors who have used the units in clinical settings will be pilloried as quacks, and visited by the people who break up or confiscate unauthorized devices like radionics instruments. People who encourage friends to use the units will be characterized as gullible, misguided "victims" of these quacks. People will be warned to avoid these "useless and / or potentially harmful" units at all cost, and doctors and researchers involved may get the same kind of treatment received by Ruth Drown — arrest, trial, and imprisonment. Rife reportedly left the country when the authorities were coming after him and left his associate behind to take the heat — 3 years in jail. The man is understandably bitter and information obtained from him is unreliable at best.

Assuming the plans for the working Rife Frequency Generator are widely distributed among people who are not doctors and have more interest in their own health than protecting the status quo, there may come a time when the establishment will become aware that these tactics have not been enough to suppress the information and the proliferation of the units among the public — who have found out that it works and keep on building it and distributing the plans free. At this point the second stage of the "suppression at any cost" plan would go into effect. Please bear in mind that these people — the ones who know and understand what this thing really is —would be motivated by possible loss of power, earning capacity, the meaning or value of their life's work, and / or the specter of economic collapse.

Stage two consists of a publicity campaign featuring people who claim to have been treated with Rife Generators at some time in the past and apparently cured of whatever ailed them. Using the wonders of technology applied to video and filmmaking, these people will be shown to have developed something *so horrendous* that cancer and radiation poisoning will appear to be mild afflictions in comparison. Medical science will, of course, have developed a preventive treatment which — if given in time — will save you from the calamitous results of your folly in ever using one of these things. The thrust of the campaign will be to convince people that if they know of anyone who owns or has ever used one of these units they have a *moral obligation* to inform the authorities so the proper steps may be taken to prevent them from suffering a similar terrible fate. People *would* turn informer to "protect" those they know and love *unless we have prepared them for the possibility of such an action ahead of time.*

Sound far-fetched? Ask any historian, political science major, sociologist, or psychologist how the "masses" are manipulated into doing and believing anything those in power want them to believe. However, you can only manipulate people who do not know what is really going on.

If the Rife Frequency Generator was a multimillion dollar unit requiring a specially trained technician to use it, it would be embraced with open arms. Its very nature would limit its application to the rich and powerful and it would be no economic threat. Rest assured that the rest of us would have no access to it. You may also be assured that during the suppression campaign it will be thoroughly checked out and will remain available to those with enough money, power, or specialized knowledge considered essential to the establishment that they will be allowed access to one if necessary — probably dressed up in a massive, totally useless housing to conceal what, and how simple, it actually is.

My point is this: historically anything that threatens the economic order is suppressed, regardless of how beneficial it is. Never before has such an object or idea been so widely distributed and so completely documented as this one. In nearly twenty years of use there have been no side effects and the benefits are apparently permanent. To suppress this will require *extraordinary measures* on a scale *never before implemented.* Previously, knowledge of how to build such instruments has been limited to a very few people, making suppression and obfuscation of the facts relatively simple. Be prepared for the possibility of such a campaign and make sure anyone who knows about and / or experiments with these units is also prepared. Informed people can neither be panicked nor manipulated.

The establishment has lost credibility with certain segments of the population and will lose ground over this. There will, however, be casualties in the battle, because there are always those who naively believe anything that so benefits mankind cannot possibly be prosecuted by the authorities. There are people who won't listen to reason no matter how graphically you explain it to them and will set up "cancer" clinics to bring the benefits of the technology to everyone. Even if you do not charge for treatments *it is against the law to heal people* beyond accepted limits, even for medical doctors. If you use one of the Rife Frequency Generators, *make certain it is clearly labeled* FOR EXPERIMENTAL USE ONLY in plain sight, that no charge is ever made for use of the unit, and that anyone else who chooses to try it *does so themselves* — you must not do it for them, *ever.*

So, build it, experiment with it, distribute the information, inform any potential users of the possible smear campaign ahead — and be prepared to claim you invoked "the Force" or prayed a lot and received a "miracle" from God, Allah, Buddha, or the Great Poobah.

Rife's Research World Savior

By ROBERT B. STRECKER, M.D.
and JOHN F. CRANE

Royal R. Rife, master of microorganisms, proved in a clinic in 1934 with a Special Medical Research Committee of the University of Southern California headed by Milbank Johnson, M.D., and a staff of prominent medical doctors in the United States, and the local President of the American Society for Pathologists, that incurable cancer could be cured in 15 to 30 days by Rife's electromagnetic method.

Milbank Johnson, M.D., Arthur I. Kendall, Ph.D., Professor of Bacteriology at Northwestern University Medical School, E.C. Rosenow Sr., Director of Research at the Mayo Clinic in Rochester, and Royal R. Rife proved in clinical tests at the Scripps ranch in 1934 that cancer and other incurable diseases can be cured permanently. Rife's virus microscopes proved that microorganisms can be studied alive in their own true colors and eliminated with (1) electromagnetic energy (2) polarity energy from cosmic and magnetic forces, and (3) color therapy from ray tube instruments. These results can stop the world's disaster from non-efficacious drugs after billions of dollars in research have shown that they have failed to help.

Dr. Royal Lee of the Lee Foundation for Nutritional Research, Milwaukee, Wisconsin, wrote about the suppression by Morris Fishbein, Secretary and Treasurer of the American Medical Association and major stockholder of the AMA and censor of electronic developments, and how he secreted Rife's virus microscopes and cancer cure from the world for the benefit of the drug monopoly, which is now killing three persons per minute in the U.S.A. and an estimated 10 persons per minute in the world. Fishbein was the editor-in-chief of Index Medicus, the American Source Index of all developments for medical doctors and Associate Editor of International Medical Index, published by Elsevier in Holland. Fishbein controlled what the medical doctor will find out and what he will not find out about any subject in medicine. All information on homeopathy, osteopathy, and chiropractic treatments was censored. Millions of people have died needlessly owing to his censorship and greed for a drug monopoly.

The information on Rife's cancer cure has been sent to Surgeon General C. Everett Koop and the National Cancer Institute and related agencies who have all failed to perform, including Representative Bob Wilson, who failed to get support. They have wasted billions of dollars for drug benefits only and the futile hope of a vaccine to aid the cause of drugs.

Research has demonstrated that cosmic, magnetic, color frequencies, and electromagnetic waves can polarize virus and bacteria and worms negatively so that they can't reproduce. Negative polarity has caused tumors to shrink. Research has demonstrated that electromagnetic energy can kill worms, viruses, and bacteria that plague animals and humans by use of electrocuting force while human cells respond favorably and are regenerated into conductors again.

RIFE RESEARCH CAN SAVE 2.5 BILLION PEOPLE IN WORLD WAR III NOW RAGING

The conspiracy of Russia to enslave the world is now being applied as a military weapon against all of humanity, in lethal biological burial in the form of cancer and AIDS plagues with no known defense possible.

Three cancer victims are now dying in the U.S. every minute. This brings in over $350-billion annually for the benefit of the medical monopolists. In the spiral of increasing deaths from AIDS, it is estimated that .66 persons will die every minute at the present time and in a year could equal the cancer disaster. Medical officials have no cures in sight for at least 20 years.

Economically, the insurance companies and medical health monopolists are being devastated by WHO (World Health Organization) and related covert monopolists as the cancer and AIDS warfare will turn to riots, uprisings, bank failures and biological disasters. Practical research must succeed in two years or less, else the AIDS and cancer incubations will finish us. We have spent over $500 billion preparing for a war that will never be fought. Citizens are dying all over and we have not recognized that World War III is even started. Half of our population is already infected with cancer and AIDS, with the cancer story "covered up". Control of the news hurts us. Ironically the government, the medical control, scientists, universities, and health organizations are too sluggish to respond in time and so stagnated that a normal 10 to 14 years can't do the job; and the military are untrained for biological warfare response.

Distribution of the viruses is now being spread by the Asian Tiger Mosquito introduced into the southwestern states to start a big explosion of the virus in two years. 65-million Africans have been vaccinated with smallpox virus containing AIDS virus which will kill all of the African people in seven years, including the animals. It is estimated that 50% of all of Africa already has sleeping sickness transmitted to Africans and animals by the tsetse fly. This is known as the trepanesome of sleeping sickness or treponema made up of parasitic and pathogenic spiral microorganisms. All of the military defense establishment cannot save a single AIDS or cancer warfare victim. The problems with AIDS and cancer victims is that the virus directly suppresses the body's natural defenses and the systems for healing, repair and regeneration. Electromagnetic force is the only way to cope with the viruses' invasions.

IT WAS RIFE'S DISCOVERY THAT VIRUS WILL SUCCUMB TO THE ELECTRON ENERGY

Electron therapy is seen as the only way to cope with cancer and AIDS viruses. Over the Rife prismatic virus microscopes the evil invasion of the viruses have been seen to succumb to the force of electrocuting voltage and frequencies from the Frequency Instruments devised by Rife and Milbank Johnson, M.D., and collaborated by James B. Couche, M.D., Arthur Yale, M.D. and many other medical doctors from 1920 to 1944, to demonstrate that all pathogenic microorganisms can be electrocuted, controlled and devitalized, without harm to the human cells owing to the fact that the cell walls of the microorganisms are about 100,000 times weaker than the human cell walls and cannot tolerate even 1 volt of electricity.

Rife destroyed the virus cells by electromagnetic energy. Rife's mastery of pathogenic diseases was described by R.E. Seidel, M.D., and M. Elizabeth Winter in "*The New Microscopes*" in the 1944 edition of the Smithsonian Report, and in the Franklin Institute: *Journal of the Franklin Institute*, Vol. 237, No. 2, February 1944, by R.E. Seidel, M.D. and M. Elizabeth Winter.

The fact that signals and magnetic energy can reverse every major cellular illness has been proven and is also in the literature on humans and animals in Rife's Research Laboratory and in human clinics by Rife and by Milbank Johnson in Pasadena for 3 years. Royal R. Rife cured cancers and leukemia with a special helium filled ray tube powered with a transmitter and audio oscillator in only a few seconds radiation time. Rife also built four virus prismatic microscopes which used interference stages with quartz optics which readily observed colored viruses stained with the color frequency of light that was tuned in by special prisms. The Rife Microscope defeated the "wavelength" limitation of the light color frequency utilized. Rife's instruments took advantage of evanescent or vanishing frequencies of color not in resonance with the virus under observation (complex waves); hence normal light wavelength was not a limitation. Phase conjugate waves were also employed. Rife discovered the exact color frequency of each microorganism for using color as a positive identification of the microorganisms. Rife then radiated the microorganisms with the color frequency and could readily destroy them. All diseases and physical troubles have been helped. The application of audio frequencies has also proven to be helpful. Conductivity in the human and animal body has been improved by electrolytes, bringing great benefits to health, through electronic applications of energy.

Government scientists have made AIDS and other viruses by crossing cancer viruses, bovine leukemia virus, bovine tuberculosis virus (1913), and visna virus and other viruses and are responsible for the current disaster in cancer and AIDS in failing to protect the lives of Americans. They have systematically barred other doctors and practitioners from using methods other than radiation, surgery and drugs which are not effective and which seal a person's fate. To cover-up cancer's disaster, they now seek to take $112-billion for AIDS in the next 5 years, claiming that victims could rise to 750,000 persons for AIDS alone.

The hospitals are now scared to death of the rising drug costs. For example the drug AZT may wind up increasing medical expenses by prolonging the lives of AIDS victims and thus increasing cost of the treatments and tests. Government labs are developing national and world-wide AIDS viruses that are given in shots to unsuspecting victims.

At public institutions for destitute victims, they all face financial ruin. Even with partial reimbursement from government programs, hospitals and care centers in high impact cities could suffer excessive AIDS costs and burdens. That already exists in the cancer cover-up. All of the health budgets are ruined owing to the unwarranted costs levied by the hospitals, drug companies, and medical experts, to take advantage of the insurance programs. Health organizations now seek to outdo the military costs of $200-billion.

Research has proven that color therapy can be of great help in curing paralysis, eliminating fevers, rallying the body defenses after other methods have failed to help, healing severe burns of the third degree type, and other miraculous benefits — though the method has been suppressed by Morris Fishbein of the A.M.A.

As the world now enters a mass destruction period, it must wake up and arise from its slumbers. Polarizers, of the cosmic and magnetic variety, electromagnetic energy, and color therapy can be verified to make the world safe for humanity. With the present conservative estimate of only 4 million Americans infected with AIDS virus, one can extrapolate that with a known doubling time of 8 months, in two years there will be 32 million Americans infected with AIDS virus. Within 4 years there could be 256 million Americans infected with AIDS virus. This could all occur before any showed any sign of AIDS infection. There is an average 5 year delay between infection with AIDS virus and any overt sign of the disease. The countries of Brazil, Argentina, and Mexico all face devastation by their purchase of blood from Africa. European countries all face oblivion — including England, France, Germany and Italy. Japan has 30 percent of selected populations infected with air-borne leukemia virus HTLV I. AIDS virus can become airborne at any time if it undergoes proper mutations. It may already have inserted itself into the genome of TB bacillus in Africa by the "Strecker Synthesis," giving rise to a highly infectious, contact contagious, and airborne AIDS combination.

With the very slim possibility that there will ever be the development of an effective vaccine for these diseases, the world cannot wait for the scientists responsible for unleashing these viruses upon unsuspecting people to find and release an effective vaccine and cure. Electronic and related developments appear as the best answer for the elimination of the AIDS and cancer viruses. If the development of these electromagnetic and magnetic modalities had not been suppressed by WHO, NIH, ACS and other drug monopolistic organizations, perhaps the world would be a much safer place to live in today.

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AIDS: URGENT COMMENTS ON MANKIND'S GREATEST THREAT AND THE SECRETS OF ELECTROMAGNETIC HEALING

by Thomas E. Bearden

Introduction

The following quote is from Don Rowe, *Wall Street Digest*, 214 Carnegie Center, Princeton, New Jersey 08540:

> "The AIDS Plague will affect society in ways that you cannot now imagine. AIDS is 100% fatal. Scientists and medical people are not optimistic about an immediate cure to vaccine. They do not expect to develop an effective vaccine within the next two decades. Public health officials estimate that as many as 2.4 billion people (half the world's population) will die from AIDS within the next 15 - 20 years.
>
> "Economically, the insurance and medical health systems could be devastated in the 1990's. Nothing short of a spectacular medical breakthrough will keep western civilization from suffering the worst catastrophe in the history of the world."

The first official U.S. AIDS case was diagnosed in San Francisco in 1981. This followed the puzzling outbreak of the disease in Third World areas such as Africa and Haiti in the 1970's. The U.S. AIDS outbreak at first seemed to be largely confined to the gay community, such as in San Francisco.

No one seemed to connect the apparently unrelated facts that, before the outbreak in the U.S. gay community, (1) the World Health Organization (WHO) had accomplished substantial smallpox vaccination in Haiti, and (2) West Coast gays — particularly from San Francisco — had made Haiti a main playground and vacation spot. Almost no one thought to notice the exact correlation between the smallpox vaccinations by WHO and the subsequent development of AIDS.

Much nonsense about AIDS has been bandied about since then. As the rationale goes, a monkey bit an African, introducing the relatively harmless monkey AIDS virus into him. This monkey virus penetrated the man's cells and combined its genetic material with that of its human host. Then, perhaps with other viruses present in the cell (to provide other genetic material), the cell's AIDS-adapted genetic material was mutated again — or even again and again — eventually yielding a virulent AIDS virus derivative or strain well-adapted to the human cell.

It is this hypothetical "monkey-AIDS virus plus mutation" AIDS that is supposedly responsible for the monstrous plague now looming to strike down half of all the humans on Earth.

That is simply not true. Orthodox scientists have not the foggiest notion why such a drastic explosion of the virus has occurred. African monkeys have had their viral diseases for thousands of years, and they have bitten Africans from time to time for thousands of years. If monkey virus were the culprit, Africa would have been devastated by AIDS thousands of years ago.

What really happened is something quite different.

In 1971, President Nixon signed into law the National Cancer Attack Act. Though certainly not intended, *the inadvertent result of this Act was that the taxpayer's funds were used to research and develop the precise things that constitute the most lethal kind of recombinant virus biological warfare.*

The on-going small effort in medical research labs to alter animal tumor viruses — including retroviruses — to replicate efficiently in human cells was drastically speeded up as a part of the new "war on cancer." Not only was the research drastically accelerated, but the *direct participation by Communists and scientists sympathetic to the Communist cause was openly accepted and encouraged.* Some of our cancer research institutes, even today, have more Communist scientists working in them than they have American scientists.

At about the same time, the KGB had mounted a major effort to penetrate Soviet biological warfare (BW) scientists into the recombinant genetics research of the Western world. They didn't have to penetrate clandestinely — we welcomed them with open arms!

In these labs, now heavily infested with Communist BW agents, animal retroviruses were injected and reinjected into human cell cultures, *until these retroviruses had developed into efficient, lethal recombinants favoring human cells as their preferred hosts.*

At that point, infection of one or more persons by one of these lethal new retroviruses could unleash a massive AIDS-like plague on all mankind. A single laboratory accident (or a single act by one Communist agent) could unleash the Great Death Plague.

All that was needed was a program that insured that the viruses could be delivered into enough humans to really get the ball rolling. And, of course, non-Soviet hands were needed to do the dirty work, so that the Soviet Union could maintain its own total innocence.

WHO Was a Godsend; Just What the Soviet KGB Ordered.

In their massive campaign to eradicate smallpox, they were already unfolding a massive innoculation campaign throughout the world — particularly in Third World countries. All that was needed was just a bit of contamination of the WHO vaccine by one or more of the lethal new recombinant retroviruses that had been developed — and were continually being developed — in cancer research laboratories *literally filled with Communist agents.*

The opportunity was ripe for the taking. The Soviets took it.

WHO carried out its 13-year massive smallpox vaccination program. Unknowingly, it also carried out a 13-year AIDS biological warfare strike for the USSR at the same time, and with the same needles.

The London *Times* Broke the Story

In a shocking article, "Smallpox Vaccine 'Triggered' AIDS Virus," in the London *Times* of May 11, 1987, *Times* Science Editor Pearce Wright announced that the AIDS epidemic may have been caused by World Health Organization (WHO) smallpox innoculations in Third World countries.

In an important article in *Easy Reader*, June 4, 1987, Jon Rappoport reported the *Times* article and the results of an interview with Robert Matthews, technical correspondent of the *Times*. According to Rappoport, Matthews informed him that WHO itself had somehow suspected that its immunization program against smallpox might be connected with AIDS. An outside consultant was employed to perform an independent study, and the study confirmed that WHO vaccines were indeed, somehow, causing AIDS to evidence in innoculated persons.

Needless to say, WHO promptly *buried* that report; its conclusion must have been the last thing WHO wanted to hear. Of course, they also fired the consultant, a man of international reputation.

The consultant then came to the *Times*. They heard him out, investigated, and printed the story. The *Times* pointed out some startling correlations, and I quote:

> "The smallpox vaccine theory would account for the position of the Central African states as the most afflicted countries; why Brazil became the most afflicted Latin American country; and how Haiti became the route for the spread of AIDS to the U.S. Brazil, the only South American country covered in the eradication campaign, has the highest incidence of AIDS in that region."

We can, in fact, make a good case that this disease is manmade. It has coldly and deliberately been unleashed on mankind by the Soviet Union, augmented by the international control groups. Further, the disease may still be being "guided," or stimulated to keep on changing, by implanted signals carried by the giant Soviet Woodpecker "over-the-horizon radars," and carried by other Soviet transmitters. Only a little of that capability will be touch upon in this paper. (July, 1987 - *Ed.*)

This Paper is Just a Prelude

In my book, *Fer-de-Lance: A Briefing on Soviet Scalar Electromagnetic Weapons*, I specifically pointed out that I was of necessity neglecting the biological warfare aspects. I intended to later write a second book covering those aspects. This paper contains the most important item of that second book, *AIDS: Biological Warfare.* (Both books published by Tesla Book Company, P.O. Box 1649, Greenville, TX 75401.) That book develops in great detail exactly how to develop electromagnetic healing. It develops in great detail the technical concepts behind everything to do. It also specifies exactly how the Prioré device worked.

As you may recall, Antoine Prioré built a strange electromagnetic treatment device, funded by the French government and under the auspices of impeccable members of the French Academy of Sciences, which cured diseases such as cancer and leukemia. The device was validated in thousands of experiments, then eventually hamstrung and destroyed by the enmity and hatred of powerful French scientists who could not understand how the machine could work, but felt their position and authority totally threatened by it.

But this paper is only a prelude to that book. It is meant to serve as a warning. I am trying to give recognition, and any assistance possible, to certain brave colleagues who (with little or no funds or resources except what they can tear out with their bare hands) are already laboring around the clock to develop a permanent solution to the AIDS problem. As a matter of discretion, I shall not mention the names of these colleagues. The solution they seek is radical, by orthodox assessment. Yet it is the only possible approach that has any chance whatsoever.

They are searching for a solution through *electromagnetic healing* — but using a different kind of electromagnetics than that taught to the conventional electrical engineer. It is my purpose here to spell out some of the path they are taking, and why that path can do what no vaccine or drug can.

What they are doing, I cannot do. If they do not succeed, no one can. But I will say this, and most strongly: in my view, the only hope for humanity lies in the work they are doing, and they have my utmost admiration and support. Let us fervently hope they succeed in their strenuous endeavor.

In my best estimate/opinion, they must succeed *in two years or less*, else the AIDS incubation already accomplished by then, and the implementation time delay —

even given a cure — together will insure a devastation of humanity unparalleled in all of history.

Curing AIDS Is the Highest Priority

Let me accent that developing this AIDS cure is far more important than developing our entire arsenal of new military weapons. It is even more important than the development of scalar electromagnetic defensive weapons. The Mideast and Nicaragua are insignificant compared to the AIDS problem.

There's no time to rail against the Soviets, who have cunningly and in great secret "struck our vitals with the mailed fist." We've been struck in such a way that, *unless we can solve the AIDS problem in two years or less, we are already finished.*

As shocking as it sounds, I am convinced that the Soviets have already launched World War III, to the hilt; and it's not at all the kind of war we've been expecting. We have been preparing to fight a better World War II. The one we're preparing for will never be fought. Instead, the real World War III is already raging, and we've not yet recognized that it's even underway.

A great Soviet "first strike to finish us" has already been accomplished. The new "Pearl Harbor" has already happened. The enemy has overrun or Maginot Line; we are at our Dunkirk. There are no boats waiting, and there are none on the way. The great Soviet first strike has been delivered with surreptitious biological warfare, not with nuclear weapons or ground forces.

AIDS is going to do the job, and other hands have unwittingly done the dirty work for them. As always in the past, we have no troops facing the brunt of the first strike and trying to turn it. This time we have far fewer than we've ever had. Just two or three.

Ironically, this time our entire system — the government, the medical establishment, the scientific establishment, the universities — all are far too dogmatic, and have far too sluggish a response time, to offer any assistance at all. They are simply so "out of it" that they don't really know what's happened. *The bureaucracy simply is so stagnated that, even with a giant paroxysm, it cannot change quickly enough to do the job in time.*

The best response the orthodox system could theoretically make — if it immediately placed the nation under martial law, marshalled all the universities and scientists, everything — would require at least seven years to produce results. A more likely response time is 10 to 14 years. That won't do the job.

So the job has to be done from completely *outside* the system. It has to be done with *independent* financing; financing without a lot of conventional, bureaucratic strings on it. Resources must be committed as needed, immediately, not with a several months' approval process. Everything in the orthodox establishment simply has to be bypassed. The government, the medical establishment, the scientific establishment, the universities — everything. Otherwise, we're as good as finished *right now.*

The Soviets Knew the U.S. Would Not React

There is information that the present AIDS viruses were deliberately created and introduced as a biological warfare campaign, at least into the African population, by the Soviet Union and possibly by the secret international control groups, as well.

Apparently, the control groups may have wished to "clean out the African continent" to provide a new continent for relieving population pressure and solving the problem of the biological time bomb — overpopulation. The Soviets, however, realized that slight changes would result in an epidemic of unparalleled proportions. They recognized the opportunity for safely initiating WW III with a great first strike. They know the U.S. is totally ignorant of scalar electromagnetic (EM) weaponry, and that the U.S. will not even be able to comprehend that it has been deliberately struck. The Soviets are quite confident of this because of the total failure of the U.S. to comprehend incidents such as the following:

(1) The long years of Soviet "weak microwave radiation" of the U.S. embassy in Moscow. The Soviets electromagnetically induced diseases that resulted in extensive health problems of embassy personnel, the death of two U.S. ambassadors, and the illness of a third.

(2) In January, 1960, Kruschev announced to the Presidium that a new, fantastic weapon was in development. He stated that the weapon was so powerful that, if unrestrainedly used, it could wipe out all life on Earth.

(3) In May, 1960, Gary Powers' high-flying U-2 spy plane was mysteriously disabled over the Soviet Union, resulting in its subsequent crash and the Soviet capture of Powers himself.

(4) In April, 1960, the Soviet Union utilized a just-deployed scalar EM weapon to destroy the submerged *USS Thresher* nuclear submarine, off the coast of the U.S. itself. In spite of intense electronic jamming experienced by the *USS Skylark*, surface companion to the *Thresher*, the U.S. failed to recognize this major indication of a scalar EM attack.

(5) In Afghanistan, in 1981 and at intervals since, Soviet helicopters have sometimes attacked Afghanistan guerrillas or villages with a strange new weapon. A body struck by this weapon dies instantly and completely. It falls like a limp rag, *and does not decay even in thirty days.* Every cell, bacterium, virus, etc., in the body has been killed instantly. Nerve gas rockets and chemical rockets are also usually fired to provide a "deception cover" for the nature of the real weapon. This eerie Soviet weapon has been mislabeled as some strange new gas, and is referred to as "Smirch" — a combination of the two words

"smert" (death) and "semerch" (sandstorm).

(6) In April, 1984, a monstrously huge scalar electromagnetic incident occurred off the coast of Japan, near the Kuriles. Subsequent interviews with the pilots sighting the event have revealed that several combined tests of the various modes of a scalar EM howitzer occurred. A giant "cold explosion" occurred, raising a giant mushroom cloud to over 60,000 feet and a greater than 150-mile diameter *in two minutes*. A glowing dome appeared, and expanded to monstrous size. According to Dr. Walker and colleagues, the diameter of this great glowing, hemispherical shell expanded to several hundred kilometers. He and his colleagues were able to rule out any possible known natural events or mechanisms that could have caused the incident.

(7) Numerous incidents of hemispherical shells of light and giant balls of light within the Soviet Union have been seen from Iran and from Afghanistan. Such giant artificial phenomena have also repeatedly been seen over the oceans by mariners and airline pilots.

(8) Several instances of anomalous disabling of jet engines of commercial airliners have occurred while the aircraft were in flight.

(9) Direct and intensive weather engineering over the U.S. itself has been accomplished by the Soviet Union for a decade, using the interference grid resulting from the crossing of two or more giant beams from the Woodpecker "over-the-horizon radar" transmitters. Specific cloud signatures (anomalous holes, giant radials, twin giant radials, and razor-sharp giant interference patterns) have continually occurred, but the orthodox system has blithely ignored them.

(10) A giant test of over a hundred huge Soviet scalar electromagnetic weapons occurred on and around May 1, 1985, for the 40th anniversary of the end of WW II. The entire Western scientific and intelligence establishment remained sublimely unaware of the huge exercise. They had not a single scalar EM signal detector — even though the air, land, and ocean was filled with hundreds of Soviet scalar EM transmitters chattering away to Soviet armed forces and submarines. Underneath our feet, the earth itself was in giant scalar EM resonance on 54 frequencies (27 pairs), each of which tapped energy directly from the molten core of the Earth and fed it to an ensemble of strategic scalar EM weapons.

(11) In late November, 1985, the Soviets tested their Launch Phase ABM system over Florida, using the launch of a U.S. space shuttle as a convenient test target. A marker beacon (ball of light) was placed in the sky, hovering near the launch area. It was seen by hundreds of persons, and photographed by George Suchary. During the final countdown to launch, a scalar EM "missile" (ball of intense energy) was fired, offset from the shuttle. This ball of energy was not in the visible spectrum, but may have been accidentally photographed by Bob Gladwin. Twelve minutes after launch, a tremendous rumbling boom echoed through the area — so huge it was heard for hundreds of miles up and down the East Coast. This was the *third* U.S. space shuttle launch in which NASA had noted associated anomalous phenomena, but it did nothing.

(12) On December 12, 1985, the Soviets used the same weapon in the anti-bomber mode to destroy an Arrow DC-8 jet just after takeoff from Gander Air Force Base, Newfoundland. Over 250 U.S. soldiers and civilian crew members were killed.

(13) On January 28, 1986, the Soviets destroyed the U.S. space shuttle *Challenger*, shortly after its launch. A dozen signatures are associated with this Soviet kill — too many to mention all of them. First, the Soviet ships monitoring the launch site suddenly departed at high speed four hours before the launch. This was unprecedented. Second, according to General Daniel Graham, the following evening the KGB headquarters gave a party to celebrate the success of their perfect active measures against the *Challenger!* Many other indicators also exist. The total is a very strong statement that the Soviets killed the *Challenger* with the same weapon they had tested against three previous shuttle launches, and which they had used to kill the Arrow DC-8 at Gander Air Force Base only six weeks earlier.

(14) A whole series of anomalous missile failures occurred, involving Titan, Delta, and Ariane launches. The odds against all these launches failing in that pattern were millions to one.

(15) In 1975, Brezhnev surprisingly urged U.S. Senators to have the U.S. cooperate in banning the development of new weapons of unparalleled horror. He used the phrase, "more frightful than the mind of man has ever imagined." Shortly after, at the United Nations, Gromyko even introduced a draft agreement for banning such undisclosed weapons, and urged all nations of the world to sign it. Again the West had not the foggiest notion as to what the Soviets were talking about.

(16) The orthodox U.S. news media has been, and is, almost totally "out of it." Ironically, at the time of our deadliest peril, and the most momentous period in history, incidents such as the indiscretions of a presidential candidate and of a television evangelist, and the sticky-fingered actions of the National Security Council in trying to get guns to the Contras, are the "burning issues of the hour" — and the week, and the month, and the year, and so on, ad nauseum.

(17) The Congress — great watchdog and the direct representation of the U.S. citizenry — is equally immersed in interminable hearings of little or no

substance except news media coverage and publicity.

(18) A lame-duck President, misled and now very much hemmed in on all sides, and on the defensive, has had his power to act greatly constricted. In addition, the orthodox filtering networks surrounding him have effectively isolated him. He has not been made aware of the extensive information that would show just how certain it is that the Soviets have fantastic superweapons and have been using them against us for decades. He and his immediate advisors are fed highly filtered, shaped and interpreted data.

Further, the intelligence community is a past master at "slick-tonguing" the interpretation of anything new, and anything they really don't understand, in terms such as "We have no evidence that..." For decades, the community has consistently underestimated the Soviet threat, and it has also usually projected any unpleasant *present* Soviet capability in the terms that "If the Soviets keep this sort of thing up, it may prove to be a real threat 30 years from now!"

For years the U.S. intelligence was unaware of a Toronto inventor's development *and public demonstration* in the late 1960's of an inertial field generator weapon, for example, *because it simply did not place high value on overt intelligence such as reading the newspapers! The entire event was printed in detail in a Canadian newspaper. Only very recently, within the last few years, has the intelligence community realized that the most important intelligence can only come from human intelligence (HUMINT) sources.*

(19) Western science has also shown itself to be highly dogmatic and ensconced in the comfortable "status quo." It has really ignored the important Soviet developments in unified field theory. It has assumed an aristocratic stance, regarding the Soviet scientists as little more than peasants still trying to clean the mud off their boots. In fact, the Soviet scientists have been ahead of the rest of the world in *nonlinear* science — the truly hard stuff — *since the beginning*. They have always been the best nonlinear mathematicians in the world.

Soviet scientific papers regularly appear which deal with *local* general relativity and the overcoming of sacrosanct conservation laws as a matter of course. That subject is still a "no-no" in U.S. scientific publications, even though the breaking of conservation laws has long been proven in particle physics. To my knowledge, with the exception of Hooper's obscurely published work, not a single U.S. scientific paper appears in the literature showing any detailed investigation of "bucking fields"*as such* and investigating the behavior of materials exposed to such "sum-zeroed" fields.

Yet, ironically, a whole area of optical physics — phase conjugate optics (PCO) — has shown great activity *since we discovered it in the open Soviet literature*, and since 1972, when two Soviet scientists visited Los Alamos and briefed our scientists on the subject! In PCO, the scalar EM wave is blithely called the *pump wave*. Using it on nonlinear materials produces extraordinary results — such as electromagnetic waves traveling *backward in time*. Further, the PC effect is known to be universal, and not just in the optics region at all. The obvious experimental and theoretical proof of Soviet scalar EM weapons has been in our literature for nearly two decades; our scientists have done thousands of experiments in it, *and incredibly, they still do not comprehend what they are really working with.*

Continually assured that Western science and intelligence remained outrageously ignorant and would obstinately persist in wearing orthodox blinders, the Soviets felt quite safe in striking the U.S. and its Western allies a mortal blow, *so long as the blow was unorthodox.* After all, the Soviets have been waging a slowly increasing *unorthodox* war against us for decades, and totally getting away with it. Consequently, the Soviets manipulated the AIDS virus to make its virulence far more lethal. They continue to manipulate the spreading AIDS viruses so that the West will be devastated, as well as Africa. In the Soviet plan, after the AIDS massacre has peaked, the remaining small U.S. and European populations will be totally powerless. The demoralized and devastated Western nations will easily capitulate and pass under the Soviet hammer and sickle.

The stimulated changes in the AIDS viruses are occurring so rapidly that producing an effective vaccine will be impossible. Without a totally new means applied to produce an AIDS cure, it cannot be done. *Orthodox methods cannot cure AIDS in time, if ever.* Unless *un*orthodox technology is applied to solve the problem, the West is already defeated.

The Asian Tiger Mosquito: A New and Efficient Vector

The Asian Tiger mosquito has been introduced into the U.S. and is rapidly spreading through the Southeastern states. This vigorous and voracious mosquito *prefers* man as his target, and has up to a 40-mile range. The Asian Tiger mosquito apparently is intended to serve as the major vector (carrier), or at least one of them, to rapidly spread the AIDS virus and devastate the U.S. population. The AIDS virus has already been confirmed living in the Tiger mosquito; however, we are supposed to believe that its bite will not give you the virus.

Let's see now... we are supposed to believe that we can catch the virus from a hypodermic needle — but not from a mosquito's *living* hypodermic needle. If you really believe that one, there's a bridge down the road a ways that I can sell you real cheap!

As the Tiger mosquito vector spreads, the *rate* of increase of the AIDS infection will itself increase. In other words, the acceleration rate of the infection is itself accelerating. This means that all the projections for "doubling times" are seriously in error.

Our government has greatly understated the problem. Officially they are still denying any possibility of insect vectors for the disease; past projections of the spread of the disease have been far more optimistic than warranted. The Surgeon-General has stated that we'll know in a few months whether or not there will be a heterosexual AIDS explosion.

The latest data from Alabama, for example, shows that the disease has been doubling every six months instead of every year. Also, the doubling interval itself has been shortening. If these and other data are a true indication, it appears that we literally may have an "explosion" of the infection *in no more than two or three years.*

More on AIDS Doubling Time

The AIDS problem is *much, much worse than officially announced*. As stated, in some areas at least, the number of new AIDS cases diagnosed has been doubling *every six months* instead of every year. This makes all previous "officially announced" estimates and projections off by several orders of magnitude (at least three).

If the incubation period (nominal) is, say, 5 years, then there is a factor of 2^{10} of *AIDS cases already in incubation.*

Remember, we've got the data only since 1981, when the first AIDS case was diagnosed. So it's statistically difficult to project ahead with any accuracy. However, the best interpretation of the data we can now make shows a spiraling (speed-up) trend in the rate of acceleration of the disease, indicative of a forthcoming asymptote. If that interpretation of the data holds true, the asymptote represents literally an "explosion of the disease." That is, the six-months "doubling interval" is slowly becoming the six-months "tripling interval," the six-months "quadrupling interval," etc.

*The best indication/projection I can tentatively arrive at is this: **If the total cure is not accomplished within about two years, then — considering the incubation ongoing by then and the speedup ahead — somewhere between a third and two-thirds of all humans on Earth will perish!***

In other words, nominally half the humans on Earth will inevitably die, say within five years (the incubation period) after that two-year point. And, most of the people who die are going to be highly selected. Most of them are going to be Westerners, Africans, and Asians.

All of our tanks, ships, bombers, missiles, nuclear weapons, and armed forces put together can't save a single AIDS victim. We've got more generals than ever before in our history, including World War II, and not one of them has a single tactic or weapon against this mortal attack. All other threats — nuclear, chemical, scalar EM, the works — pale in comparison to this doomsday weapon that has already been unleashed upon an unsuspecting world.

World War III Is Already Raging

*World War III **has long been unleashed and a final, decisive first strike has now occurred.** We've already lost the war unless unbelievably heroic measures are taken immediately!* This thing is deliberate. It's fiendishly clever. It's effective. And a smiling Gorbachev — master propagandist — is just part of the icing on the cake to deceive us until it's too late.

Ironically, Soviet propagandists have cleverly started claiming that the U.S. has produced the AIDS virus and unleashed it. That's a very clever propaganda trick to shift suspicion from themselves.

Unless we move immediately to effect a total cure, the armed forces of all the Western nations will shortly be devastated. We surrender. We lose. The Soviets get the U.S. farmland. That's what they really need. Of course, they will also have rid themselves of about 200 million Americans or so along the way.

That solves the old "winners problem" of what to do with a conquered, resentful populace. That problem will have already been taken care of, for the U.S. populace will essentially have been eliminated. There won't be many U.S. military prisoners, for most of the military personnel will also have been eliminated. Remember always that the Communists' doctrine is to wage a total war...win any way, with any weapon, at any cost.

And Communism is an oligarchy — a religion in power in the state, and using the state's power to enforce its religious goals. Communism has always taught that it is necessary to *destroy* capitalism, That equates with destroying the U.S., the major capitalist country. Communists have always taken the long view, willing to struggle for decades to eventually accomplish their aim.

If you think no modern nation could be so incredibly savage as to deliberately destroy untold millions of people, look at the actual record of the Communists.

- When the Khmer Rouge took over Cambodia *they murdered a third of their own people.*
- The Soviets murdered millions of their own Kulaks when they collectivized the Soviet farms.
- The Red Chinese also slaughtered Chinese peasants by the millions — perhaps as many as twenty million — when they collectivized the farmers.

Lenin's followers have proven over and over that they are capable of murdering many millions of persons — even their *own people.*

Dedicated Communists are highly religious persons, even fanatics. Deliberate murder to achieve Communism's goals is part of the accepted dogma. The Communists are quite capable of killing a couple of billion "foreigners" and "enemies," given the chance.

The opportunity to strike the final blow with as simple and unorthodox a weapon as the AIDS virus could simply not be *ignored by men who have spent their lives trying to maneuver the world into a situation where just such an opportunity presents itself.*

Western Medicine is Inadequate

Present Western medical science is totally inadequate to do the task required. For example, present medicine is largely based on "slowing or killing the invader of the body," whether the invader is a germ, bacterium, virus, or whatever. We've been conditioned by allopathic medicine — and by the big drug industry — to think chemically of disease. We have been conditioned to forget that ***all chemistry is based on, and controlled by, electric charge and charge distribution.*** If you control the charge and the charge distribution, you control the biochemistry — of the cell, of the body, *all of it.* And, you can control the charge and the charge distribution with scalar electromagnetics.

If there's a *mechanical* difficulty, the present treatment is to try to mechanically remedy it — remove a bad appendix, set a broken leg, etc. However, *then* it's strictly up to the body's own natural healing system — its immune system and its repair system — to actually do the healing and repair/reconstruction. Our present medical science doesn't even know what makes the healing and repair system tick.

They still think chemically; so they've really gone gah-gah over brain endorphins and other "control" chemicals. They haven't got the foggiest notion of what kind of control system directs the production and control of the endorphins — what regulates them.

The problem with AIDS is that it directly affects and suppresses the body's systems for healing and repair. Even if a way is found to destroy the AIDS virus, present medicine has not the foggiest notion of how to restore the healing and repair system from the damage and destruction it will already have sustained.

Compare the situation to division combat. Hostile invaders are at the front of the division and by the division's combat forces. A battle ensues, with penetration and damage to the rear area support and sustenance facilities. After the enemy is beaten back or destroyed, the rear support and the combat forces must be renewed and restored. If that cannot be done, the seriously weakened division can literally be bowled over by almost anything that comes along and hits it.

Modern medicine has almost no tools or means of restoring the support and rear maintenance functions. Even in a paroxysm effort, dogmatic Western medical science would take decades to totally reorient its medical thinking to where it could even attack the real problem.

This also applies to our governmental bureaucracy, governmental agencies, private companies, the universities — and to Western science in general. If we have to depend on any or all of our present "system," the war is already over and we are already doomed. Half of humanity will die in possibly 5 years after the upcoming two-year "point of no return."

Medical insurance, treatment centers, and even private physicians are going to be bankrupted quickly as the AIDS plague increases. With the collapse of Western medicine, panic and pandemonium will reign in the streets. Martial law will be a necessity, and rioting on a scale unparalled in American history will occur. We are likely to see our own dictatorship, in the form of a military junta making a coup and seizing power "to restore order."

Study carefully the performance of governments and military regimes in such countries as Korea and South Vietnam, when they were hard pressed by enemy forces and in great disarray. There you saw the universal rise of dictatorship to respond to the stress. Look carefully, for you are looking at your own future.

With the devastation of our armed forces, governmental and civil agencies, and our population at large, a simple show of strength by the Soviets will collapse any further resistance. The hammer and sickle will wave supreme over the residue. *That's because the Russians do have the necessary developed scalar EM technology* — they call it "energetics" — not only to control and destroy the AIDS virus, but also to directly restore the immune and repair systems.

Unless a totally different tack is taken in the Western effort to counter this threat, Gorbachev's entrancing smile has already lured us to our doom. We are faced with a direct realization of Lenin's words:

> *"In the final revolution it does not matter if three-quarters of the Earth is destroyed, so long as the remaining quarter emerges Communist."*

And Kruschev's ghost will have the last laugh after all. We will have fulfilled the prediction he made to Nixon in their famous "kitchen debate:"

"We will bury you!"

There is Hope that We Can Stop Aids

It isn't hopeless. Preliminary results have already been obtained, and they are most promising. However, let me warn that these results are only preliminary. There still is an enormous amount of work and testing before it is really known for sure. But at least, right now, in the preliminary tests they have zapped viruses, harmful bacteria, lethal protozoa, the works — with miniscule voltage — all without doing any harm at all to the normal human cells, including blood cells.

In the West, there are only perhaps a dozen or so persons that I know of who are qualified to work on the essential pieces of the primary scalar EM work required. They are all unorthodox researchers and scientists. There are thousands of fine orthodox scientists, of course, who can help with the normal peripherals — making and testing viral solutions, setting up and operating equipment, doing interminable tests, all the lab stuff, etc. But only about 12 unorthodox guys are qualified and prepared, mentally and emotionally, to come to grips with the particular scalar EM technology required for rapid development of an AIDS cure. Right now there are just two or three of the 12 working on this, hammering away as best they can, at terrible cost to themselves and their normal endeavors.

The expanded scalar electromagnetics can solve the AIDS problem, if it can be developed and applied quickly enough. Royal R. Rife and Antoine Prioré have already shown the way.

There must be money enough, authority enough, and power enough, to marshall the actual persons needed, by name. If substantial funds can be secured quickly, the exact team necessary can be put together in time to probably succeed.

The Master Cellular Communication System

Dr. Fritz Popp has already discovered and pointed out the "virtual state" master communication system that controls all cells in the body, and all their functions. This is a **scalar EM system.** Its electrical conductivity path is not through the electron shells of the atoms, but is directly through the nuclei-to-nuclei scalar EM pathway.

With scalar EM methods, organized signals (signals with specific internal nonzero vector EM waves, but which externally sum to zero vector resultant E and H fields) can be constructed for essentially any specific purpose. This includes "killing" a cancer or leukemia cell, destroying a virus, changing the DNA, etc. This approach can directly reach and manipulate all immune and repair system functions. The entire biochemistry and functioning of the cell — including its genetics — is totally engineerable.

Further, a specific "charge pattern" of desired specific immunity can be designed and used to "charge up" the nuclei of the biosystem. This charge is then maintained by the system to provide permanent immunity.

The Nature of Mind and Thought

The reason Western science has not discovered what mind and thought are is simple — they have only built instruments and tools to look *where the mind and thought are not to be found.*

Let's look where they *are* to be found. For example, consider the ionic discharges in and across the tremendous numbers of synapses of the human nervous system, and the slower discharge and migration of ions across cellular membranes, etc. Considered as a single biological ensemble, these are much like a vast array of continual and continuing spark discharge vectors, slow charge current vectors, etc. Overall, within the macroscopic space occupied by the body, these electromagnetic vectors sum almost entirely to a zero vector resultant. Only a tiny nonzero vector residue remains. However, this vector zero summation has incredibly rich infolded signals, channels, and dynamic relationships (structure) within it.

This zero-vector summation is the *biopotential* of the body. It is constantly and dynamically changing. For the esoteric-minded, this is the real aura. It has multiple virtual-state levels. It is anchored in, and resides in, the *atomic nuclei* of the mass of the body. It is a virtual-state engine, activating, structuring, and dynamicizing the virtual particle flux of the charged particle of the body. Hence it "fine-structures and dynamicizes" — and controls — the body's charge and charge distribution. In that fashion it controls and directs the body's biochemistry.

Modern science/medicine measures the small *nonzero electromagnetic residue* (the remaining weak E and H fields) and tries to ascertain where and how mind and thought are accomplished by that residue.

That's the wrong ballgame, and the wrong ballpark.

The residue E and H field remainders are simply the garbage thrown out of the glorious engines ***dynamically operating inside the vector zero summations.*** The E and H field residues are the wastes or exhaust byproducts. They are not the functions of the mind/thought process itself; instead, they are the *spillage* or *leakage* from those functions.

Now let us look at what **thought** is.

Take a "frozen time" snapshot of the components of the zero vector summation. Regard the highly complex, infolded *structure* or *pattern* these components form.

Now take a second "frozen time" snapshot of the components of the zero vector summation a very, very short time later. Subtract the previous "frozen pattern" from this second "frozen pattern." The difference or delta between the two patterns represents a myriad of *thoughts* or *specified forms in the virtual state.* Hence, it represents the contents of the "thinking mind" in the most general sense.

The *mind* is the overall functioning and changing of the entire pattern's substructure, and the ability of an organism to have such and do such. The "ability of the organism to do such" requires at least two more nested levels of virtual states — two more more additional hyperdimensions, which is the same thing.

In Kaluza-Klein theory, all those electromagnetic component vectors are in the fifth dimension. Hence, they are hyperdimensional. Everything driving the vectors themselves is higher dimensional.

A thought is the exact change of a localized pattern (localized zero vector summation whose components are changing but remaining zero summed) from one moment to the next. Thought is always a *pattern change,* of the components inside an EM vector summation.

Most thoughts are totally "unconscious" (multiple simultaneous or "parallel" thoughts). A few are conscious (serially ordered, singularly considered and processed). The unconscious mind is totally a parallel processor (many things/thoughts at once). The conscious mind is totally a serial processor (only one thing/thought at a time).

Most persons never take the time and trouble to reflect and notice that, *consciously*, they can only perceive one single thing at a time. Of course, the conscious mind is so rapid that by habit they assume they can perceive many things at once. Since the conscious mind cannot discriminate the "multiple images in the slide projector at once" of the unconscious mind, that's what makes it unable to "be conscious" of the contents of the "unconscious."

In fact, the unconscious mind is totally conscious — it's just *multiply* conscious simultaneously. (Which sheds some interesting light on why one can develop multiple personalities, for instance.)

When the conscious mind "regards" the unconscious contents, it sees "something" which has "multiple meanings at once." That's what we call *symbolic. A symbol is something which can have many meanings.*

That's why the unconscious content always "symbolizes" something when it's trying to communicate to the conscious mind. It's necessary to interpret the symbols to understand the message being communicated.

That's why dreams, for instance, are symbolic; and why it usually takes a trained psychiatrist or psychologist to properly interpret the symbolic representations manifested in mental disorder and get at the underlying cause being symbolized.

With deliberately constructed scalar electromagnetics, any or all of the conscious/unconscious portions of the mind can be available for engineering and control/change.

Note that the ensemble of sum-zero vectors forms potentials. These potentials (i.e., the scalar EM) penetrate to the nuclei, and internal changes in the potentials' substructures (i.e., thoughts) also penetrate to the nuclei.

The nuclei continually charge up; the particles change their states, to the impressed potentials, including the potential or charge of *each component of the impressed potential.* The nuclei charge up with both dynamic overall potential (mind) and thought (individual substructure changes).

Note that mind, thought, and memory *reside in, and are recorded in, the atomic nuclei.*

The dynamic mind/biopotential uses negative energy and negative time, since the nucleus is positively charged. Positive energy and positive time are *negative charge* creations — that's what you get from photon interaction with the electron shells of atoms.

Since it operates in negative time, the mind/biopotential is *negentropic.* It can restore order from disorder. In that way, the "life blueprint" of the living organism can maintain order in the midst of the entropy of the normal physical components of the physical body.

Thus the functioning mind and bio-control systems — including Popp's master cellular communication system, the immune control system, the acquisition control system, and the repair control system — all "reside" in the nuclei as dynamically interacting, patterned potentials or "patterned charge," complete with resonances and frequencies, etc.

The Prioré Machine

Funded by the French government in the amount of several million dollars, Antoine Prioré built an electromagnetic treatment machine and concretely demonstrated a nearly 100% cure for all kinds of terminal cancers and leukemias, in thousands of rigorous laboratory tests with animals. These tests were shown to medical scientists as early as 1960.

Into a tube containing a plasma of mercury and neon gas, a pulsed 9.4 gigahertz wave modulated upon a carrier frequency of 17 megahertz was introduced. These waves were produced by radio emitters and magnetrons in the presence of a 1,000 gauss magnetic field. Experimental animals were exposed to this magnetic field during irradiation, and the mixture of waves (some 17 or so) coming from the plasma tube and modulating and riding the magnetic field passed through the animals' bodies.

Among other things, a plasma can convert a transverse wave to a longitudinal wave. Also, phase conjugate (time-reversed) electromagnetic waves can be produced. The Prioré apparatus produced a scalar EM wave/signal with deliberately constructed, infolded components, including phase conjugate EM waves.

Phase conjugate EM waves carry negative energy and negative time. They exhibit negentropy, and move from disorder back to order. The proof is already in hundreds of technical papers in nonlinear phase conjugate optics in the orthodox scientific literature.

Every cell has a complicated electromagnetic radiation spectrum. An abnormal cell has an abnormal change to that spectrum. If we subtract the normal cell's spectrum from the abnormal cell's spectrum, we have a specific "delta" which, when introduced to a normal cell, will convert it to that kind of abnormal cell.

When we have such a signal pattern for cancer conversion, for example, we can irradiate a normal cell with it and turn that cell into a cancer cell.

Now, however, suppose we phase conjugate that "cancer conversion" signal pattern. The phase conjugate replica will be the pattern that precisely converts that sort of cancer cell back to a normal cell!

If phase conjugate replicas of a cancer cell's specific delta frequencies are fed into the cells of a body having that cancer, the cancer cell's master cellular control system will be modulated with these "time-reversed" specific signals. That will return the cancer cells in the body to the control of the animal's proper master cellular control system. The cancerous cells will be immediately destroyed, or reverted back to a normal cell of the animal.

A very similar process exists for just about every disease virus, bacterium, and infectious agent — including AIDS! In simplified terms, if an action in forward time *induces* a condition, then the time-reversal of that action will *reverse* the condition. The concept is almost laughably simple. *Time-reversal of an electromagnetic disease process is a specific electromagnetic healing process for that disease.* That's how my colleagues are striving to develop a cure for AIDS — and for cancer, leukemia, and just about every disease known to man.

In his device, Prioré internally structured the carrier photons themselves — making them "vacuum engines." This structure contained the dynamic "delta" for the disease. By introducing these spectra into a giant rotating plasma, he phase conjugated his vacuum engines, and then passed these time-reversed vacuum engines down and through a strong magnetic field which thoroughly penetrated all cells of the biological organism being treated.

The scalar components (structured photons) representing the time-reversal of the disease were absorbed and reradiated in all the cells, "charging up" the nuclei of the atoms in the organism to some potential level of that exact "healing and reversing pattern."

In that way, he passed a specific "cancer reversal" phase conjugate replica into every cell of the body, charging the cellular biopotential and inducing a permanent "healing delta" onto the body's cellular master control system. In the process, the cancer/leukemia pattern/charge in the nuclei was cancelled or "discharged." The new time-reversed charge also *destroyed* the cancer cells, or converted them back to normal cells, as appropriate.

That cured the disease — even terminal cases — 100%. Prioré could also cure sleeping sickness, leukemias of all types, and even clogging of the arteries.

As a highly simplified analogy, the complex healing signal — viewed as a scalar Fourier expansion — represented a "stress" against any cellular control system delta encountered, to return to the normal cell's master cellular control system of the body. Encountering the normal control system in normal cells, there was no delta, so it produced zero stress. Encountering the abnormal control system in tumorous cells, it produced great specific stress on it, reverting it to the normal control system of the body's normal cells. If the cancer cell could not withstand the stress, it died.

Thus, to a normal cell the Prioré signal pattern acted somewhat like a comb passed through one's hair. No interference occurred with the normal cell (one whose scalar control pattern is phase-locked to the body's master cellular control system and phase-locked with it). The Prioré signal stimulated and "stroked" the normal cell, but did not hurt it at all.

On the other hand, the scalar control pattern in and of an abnormal (cancerous) cell is out of phase with the body's master cellular control system, and is not phase-locked to it. Hence, the Prioré signal caused direct interference with the abnormal cell's *independent* scalar control system. The interference pattern constituted the reconstruction of normal energy directly in the cancerous cell, and also jammed its abnormal scalar life signal.

This destroyed the cancerous cell by two mechanisms: (1) physical energy was kindled directly in the abnormal cell, causing direct mechanical damage, and (2) the cancerous cell, being an "independent living critter" had its scalar life channel (connecting its primitive "mind" to its "body") jammed and stopped. If the cancerous cell was reverted to a normal cell by the Prioré stress before being destroyed, it became just a normal cell and the Prioré stress had no further effect upon it.

Any disease with cellular, biochemical, or genetic basis can be cured in like fashion.

Prioré's method, for example, was clearly shown to be able to completely reverse clogging of the arteries with fatty deposits, and to be able to lower the cholesterol level to normal, even in the presence of an abnormally high cholerestol diet. His method also showed complete mastery and cure of sleeping sickness and trypanosome-induced illnesses.

Prioré found that every cell of the body — even the hair — must be irradiated and treated (charged up) with the signal, for the disease pattern is in every cell. The master cellular control system is *holographic* — the *pattern* (substructered potential with its dynamic, oscillating components) is in each component (each atomic nucleus, hence in each cell). Every structural level of the body larger than the cell also has its own correlated pattern, or modulation, on the overall.

A biological organism can regenerate lost limbs, for example, if it can utilize its natural recovery process in a Prioré manner.

Even though Prioré's work was presented to the French Academy of Sciences by Robert Courrier, head of the Biology section, the Academy could not understand the device and its functioning. That was because *the Academicians knew nothing of scalar electromagnetics, and phase conjugation, and the Prioré machine was a scalar electromagnetic device using phase conjugation.*

In 1974, a change of local government lost Prioré his government supporters and funding. Ironically, Prioré was just completing a 4-stories-tall apparatus capable of radiating and treating entire human bodies. It would have been capable of curing cancer and leukemia in humans rather than just in laboratory rats. (His previous machines were much smaller, and only a small animal could be irradiated whole-body.) In that machine Prioré used a "lamp" — a special section in which 17 specific frequencies were mixed and modulated upon the 9.4 gigahertz carrier. It should have been capable of curing cancer and leukemia in *two five-minute irradiations, one week apart.*

While Prioré was still alive, with my associates I spent nearly two years of my life in an effort to bring the Prioré device to market and into the mainstream of medical research and development. Verbal agreements with the Prioré group and with the French government were obtained. The machines were to be built, assembled, and tested in Bordeaux. Then they were to be dismantled and shipped to the purchasers — large medical research and development laboratories.

Mysteriously, all funding for the project was suddenly withdrawn. Our backers were leaned on very hard. It seems one does not finance a simple cancer and leukemia cure and live to tell about it.

Prioré never again recovered his funding, and later died. The machine fell into disarray and was disassembled. However, the proof that the requisite time-reversed signal can be produced, and will ride down a magnetic field to penetrate every cell in the body, is already in the present hard-core physics literature, if one knows where to look and how to properly interpret the work. The fact that such signals can reverse nearly every major cellular illness condition in the body has also been proven and is in the literature.

The Prioré-type cure for AIDS only requires the necessary funding, and *assembly of the exact persons, by name, necessary to do the job.*

The Kaznacheyev Work

The Kaznacheyev experiments in the Soviet Union proved that *any* cellular death and disease pattern can be induced by a specific pattern carried on an electromagnetic signal, if the target cells are bombarded with the pattern-carrying carrier signals for a length of time. Over 15,000 experiments were done in several military institutes.

The Soviets reported the effect using near-ultraviolet photons as carriers. The UV photons were those emitted in death by a diseased or damaged cell as it dies — that is, the bioluminescence (which carried the properly substructured photons). Bombardment of a target cell culture by the "death pattern photons" (remember, these *conditioned* photons are specific vacuum engines) induced the exact disease pattern in those cells after a "charge-up" or "kindling" period of time. During that charge-up time, the atomic nuclei in the target cell culture was gradually introduced onto the master cellular control system of the cells in the target culture.

Scientists with whom I correspond, at the University of Sydney, Australia, have fully replicated — and extended — the Kaznacheyev experiments. They have induced cellular death and disease between cell cultures at over 100 feet distance, which happened to be the convenient distance between two buildings. University of Marberg scientists in West Germany have replicated the Kaznacheyev effect in the infrared (i.e., with infrared "conditioned-photon" vacuum engines).

Note particularly, that it is already well-known in quantum mechanics/electrodynamics that, when a photon is emitted from the surface of a dielectric body, *the entire dielectric body* participates in that emission. If a photon is absorbed on the surface of the dielectric body, the entire dielectric body participates in that absorption.

What was not published of Kaznacheyev's work was the correspondent Soviet work showing *electromagnetic reversal of cellular death and disease conditions by irradiation by phase conjugate replicas of the pattern-carrying induction signal.* The burning question as to whether cellular disease conditions can be corrected by time-reversed signals must certainly have occurred to the Soviets, *since phase conjugation was already being widely utilized in their giant scalar EM weapons.*

It is certain that they thoroughly investigated this medical potential. It is highly significant that they did not openly publish *those* results.

Royal R. Rife's Cancer Cure and Microscope

Royal R. Rife cured cancers and leukemias with a radiation from a special gas-filled ray tube, in only a few seconds radiation time, in the 1930's and 1940's. He also built a microscope which used over 20 interference stages with quartz optics. The microscope is important, because it used a special kind of electromagnetics — *evanescent waves*, or waves with only hyperdimensional components — **to totally transcend the wavelength limitation on optical resolution.** Consequently, it could see directly into the virtual state, past the photon limit.

Today we can show learned papers in the scientific literature proving that this is possible. In Rife's day, it was considered total heresy, if not downright lunacy. Present forefront physics has now proven that the wavelength limit in optical instruments can be violated by utilizing *evanescent (complex) waves*. Rife's microscope in fact utilized such waves; hence normal light wavelength was not a limitation. When an instrument is utilizing complex waves, it can also easily be utilizing phase conjugate waves.

Rife's microscope could, in fact, see directly into the virtual state itself. Indeed, with it he could not only see the exceedingly small "point" cells that lie between ordinary cells, but he could see and *identified sixteen internested deeper and smaller levels of structure within the point cells, which are themselves just barely visible to the finest optical microscope today.*

Nothing before or since has achieved such a penetration. In his microscope, he could see living virtual state energy forms, functioning and moving. The biology his microscope revealed was far beyond the state of biology today. *With it he could see — and learn to manipulate and control — the living internal structure of living electricity.*

Since internested levels of virtual state are also higher spaces (hyperdimensions), Rife's microscope was the first and only instrument to see *directly into higher dimensions,*

and observe higher dimensional living forms.

He found "living energy" forms — critters, if you will — inside the virtual state that could go through the finest filter, reconstitute the bacterium or virus on the other side, and produce the actual disease itself — with or without the bacteria or virus. These critters were living things, though quite different from what we have been taught in biology class.

Indeed, the critters are "living electricity" or living charge, and assemble in and around any living thing, such as a virus or bacteria. They interact between the material observable state and the virtual state, including the chemistry of the cell and body. Being living structured electricity, they can be manipulated by structured electricity. And, they can be "killed" or destroyed by structured electricity.

But you have to have internally structured electromagnetic waves to induce internally structured charge into the cell and the body's biochemistry to affect and negate the structured critters. That's a *scalar electromagnetics* process. With that kind of process, you can cure AIDS, cancer, leukemia, sleeping sickness, malaria — or anything else.

Rife's microscope also could be utilized to determine the exact "color" (specific frequency pattern) associated with a particluar virus, bacterium, and disease organism. He could then irradiate the organism with this frequency pattern and destroy it readily. His work was thoroughly checked and widely reported.

In Rife's time, such a thing was unthinkable to medical science. Yet today, with substantial evanescent wave technology already utilized in waveguides, and with a well-developed body of evanescent wave theory, we can conclusively prove that Rife's microscope was capable of doing precisely what he and other scientists reported.

For his efforts, Rife was hounded into prison. He was later released a broken and discouraged man, living out the remainder of his life and dying quietly. Rife produced a cancer cure, and they quickly destroyed him for that. But his work is not dead; it lies dormant.

Rife's work can be recovered, replicated and resumed, however, since there are one or more persons remaining alive who have intimate knowledge of his equipment and techniques. Also, one or more of his original microscopes is still in existence and available. Repair on it is proceeding now. With the grace of God, my colleagues are already well on the way to reviving his work in order to stop the AIDS virus.

Ruthless Suppression of Electromagnetic Healing

Deliberate suppression of electromagnetic medicine has repeatedly occurred in the West for several decades. This suppression has been, and is, particularly severe in the United States. Conventional U.S. medical dogma proclaims that any claim of "electromagnetic treatment" is fraudulent.

This is particularly asinine since, with the advent of quantum mechanics in the 1920's it was clearly established that all chemistry/medicine, and even *mechanical force itself* is based on electromagnetics — specifically, upon particles of mass and their exchange of virtual particles. Rigorously, in quantum mechanics *everything* is simply dynamic patterned structurings in potentials, with virtual particle exchange between vacuum and observable particles in physical systems. Chemistry, for example, is totally based upon, and controlled by, charge and charge distribution. With *scalar* electromagnetics, charge and charge distribution can be totally controlled.

Indeed, contrary to ordinary quantum mechanics and electromagnetics, in scalar electromagnetics the "charge" and the "potential" themselves can be deterministically structured to comprise *deliberate vacuum engines to accomplish specific purposes — in the nucleus, in the atom, in the molecule, in the material lattice, etc.*

But, unless medical science frees and funds research in electromagnetic medicine, scalar electromagnetic medicine will never be developed and applied.

At any rate, Western pioneers in electromagnetic medicine have been hounded, ostracized, penalized, imprisoned — and even killed. Make no mistake — there exists a cancer cartel that curdles one's blood. In the U.S. alone, 500,000 persons die every year from cancer and leukemia.

A cancer patient, on the average, may represent $30,000 to $50,000 or more "on the hoof" (or on the "slab"), and the price is rising every day. That represents a lot of money to certain vested interests. Stupendous investments in chemical (drug) medicine have been made, and an extremely large income results from the consumption of those drugs by medical patients. Medicines, drugs, and medical science have become a gigantic "consumer industry."

There's no way the present vested interests are going to let something potentially as simple, quick, and cheap as electromagnetic medicine kill the goose that's laying all the golden eggs.

But, if you're a medical doctor and practicing the prescribed dogma, you can burn the hell out of the patient with nuclear radiation and chemicals. You can slash the hell out of the patient with extensive and repeated surgery. In those cases you're a stalwart hero — even if the patient suffers untold agony and a horrible, inevitable death.

But you can't try to treat them with — or even develop — a gentle, non-burning, non-slashing, type of treatment such as electromagnetics.

Understand, I'm not blaming the individual doctor himself. He's doing the best he can. Most of them are as agonized as we are over all these horrible deaths.

The vested interests have determined what the doctor knows how to do, what tools he has to work with, and what he ***is allowed*** to do in the first place. The high priests of Western medical science should consider one point which is implicit in their own teachings, but most blithely ignored:

> *After all the cutting, slashing, burning, and drug poisonings are finished, any healing of the organism is totally accomplished and controlled by microvolt and millivolt electromagnetic control systems in the body, and the living electrical substructure of those biopotentials. Nothing the present medical science does is healing, in the truest and strictest sense.*

Some Major Points in Summary

The blunt points are these:

(a) Only the electromagnetic (scalar EM) approach can do the required task, at all. Even more so, it's the only approach that can do the job in the required time (2 years).

The necessary ingredients for the job have already been demonstrated, though not properly understood. Work by Rife, Prioré, and others has clearly shown that cellular disease can be cured electromagnetically. Phase conjugation and Kaznacheyev's work point the way to a direct cure for AIDS.

(b) It is totally impossible for the present system to do what has to be done, because of its dogmatic and obstinate attachment to a false god of medicine and far too lengthy procedures. As Anton Wilson said, "What you believe imprisons you." Orthodox medical science is imprisoned by its own belief (dogma) and its directors will literally fight to the death of all of us to preserve those beliefs. Indeed, so will the directors of the orthodox scientific community.

(c) Unless an electromagnetic treatment development is started on a crash basis, the West is already doomed, and half of humanity will die. World War III is already won by the Soviets, unless we launch an intense scalar EM effort to develop a quick and effective cure for AIDS. *It has to be done by unorthodox scientists, for a few of them are the only ones who have any knowledge at all of scalar electromagnetics.*

(d) As far as I know, only about 12 persons or so in the West are *qualified* for the primary work. Hordes of other scientists and researchers, however, can do much of the peripheral and experimental work. Almost all of the "dirty dozen" are unorthodox researchers — some of them little known or unknown. An initial intense program to indoctrinate additional openminded *orthodox* scientists on the team, of course, would be mandatory.

(e) Substantial and quick funding is absolutely essential if this effort is to begin in time to succeed. The unorthodox researchers themselves do not have such funds, nor do they necessarily have the connections to raise them.

(f) *This is a matter of the highest national and world priority.* AIDS was deliberately launched against us by the Soviet Union — at least in my firm opinion — as a fiendishly clever biological warfare strike *which is guaranteed to do the job it has been specifically tailored to do.*

Unless we counter the strike — AIDS — everything is lost. Our army, navy, air force — indeed, all the armed forces of the West — are powerless, meaningless, and futile against this threat. *Nothing the Western defense departments are presently spending, funding, developing, or considering is of any meaning whatsoever, unless we meet this pre-eminent threat and overcome it.*

May God help us all. Unless we move on this, and exert ourselves to the absolute limit, the Free World and half of mankind are doomed.

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CANIN #13	candidiasis internal
CANEX	candidiasis external take by mouth
CANEY	candida eye take orally
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THE RIFE REPORT
A GLIMPSE TO THE PAST FOR
A VISION TO THE FUTURE

Due to the proliferation of Chronic Fatigue Syndromes, Mononucleosis, Epstein-Barr, environmental illness, Allergies, Candida Albicans, AIDS, Herpes B and other chronic diseases considered unmanageable with antibiotics or orthodox therapies interest is being directed toward other alternatives. One such alternative is a technology invented by Royal Raymond Rife of San Diego, California.

The article which you are about to read is a summary of over 50 years of researh by Rife (1888-1971), who according to several investigative reporters and authors may very well be the founder of the new era in medicine.

The entire story is revealed in the book, "The Cancer Cure That Worked, Fifty Years of Suppression" By Barry Lynes a top investigative reporter from Washington, D.C. and John Crane an associate of Raymond Rife. This report is a summary of that book. The full details of this summary report will keep you spellbound, bordering on disbelief as you discover what may very well prove to be one of the greatest scientific breakthroughs in the history of medicine. THE RIFE FREQUENCY INSTRUMENT.[1]

SUMMARY

Raymond Rife, as early as the 1920's, had developed not only the technology to see disease causing pathogenic micro-organisms, but invented an instrument to successfully neutralize and eliminate these pathogens which cause most diseases. Rife's instrument according to Author/Scientist T. E. BEARDEN, "revolutionized everything that has been done before or since in cellular biology. The instrument could very well be the only existing solution to the AIDS problem.[2]

Simply put and without technical jargon, Rife's work produced the most powerful microscope ever invented to detect disease and an equally powerful device to correct it. Specifically Rife invented:

* A microscope that could see through the use of color refraction, the biological life process of pathogens such as viruses, bacteria, fungi at over 60,000 diameters.

[1] The Cancer Cure That Worked, Fifty Years of Suppression by Barry Lynes and John Crane, Marcus Books 7S Tidefall Dr. Toronto, Canada M1W 1J1. 1987 (416) 494-6771.

[2] AIDS Biological Warfare by Thomas Bearden, TESLA Book Company, P.O. Box 1649 Greenville, Texas 75401, 1988.

* An electromagnetic instrument that was able to eliminate these pathogens using a specific electronic frequency (much like the TV commercial where a Memorex taped voice shatters a glass).

* The combination of the microscope and frequency devices resulted in the ability to observe and determine what electronic frequencies neutralize what disease processes.

Royal Rife's discoveries were first encouraged by the medical establishment. Special studies were conducted by several leading universities, research institutions and in the clinics of nationally known researchers and top ranked clinicians.

A special medical research committee was established at the University of Southern California to oversee and report to the medical community the results of the clinical trials being conducted by Rife and several doctors at the Scripps Institute Ranch in La Jolla, California. Members included:

* Dr. M. Johnson (M.D.) Chairperson of the Committee, Medical Director of Pacific Mutual Life Insurance and President of the Los Angeles County Medical Society.
* Dr. K. Meyer (M.D.) Director Hooper Medical Research Foundation, University of California School of Medicine (San Francisco).
* Dr. E.C. Rosenow (M.D.) Department Chairman Mayo Clinic Rochester, MN.
* Dr. G. Dock (M.D.) Tulane University School of Medicine Louisiana.
* Dr. C. Fisher (M.D.) Children's Hospital, New York City.
* Dr. W. Morrison (M.D.) Medical Director Santa Fe Railroad Los Angeles.
* Dr. O.C. Grunner (M.D.) McGill University Cancer Center, Montreal, Canada.
* Dr. A. Kendall (M.D.) President and Department Chairman Northwestern University School of Medicine, Chicago, IL.
* Dr. A. Foord (M.D.) President American Association of Pathologists.

Also involved were over 90 independent medical doctors in the U.S. and Canada who worked to establish techniques, methods and conduct clinical trials of the frequency instrument.

The reports of the technology were reported in:

* Science - E.C. Rosenow Vol. 76, August 26, 1932, pages 192-193.
* Science Newsletter - Vol. 33, January 22, 1938, page 55.
* California and Western Medicine - Vol XXXV No. 6, December 1931.
* Mayo Clinic Bulletin - Proceedings of the Staff Meeting of the Mayo Clinic Vol. 6 No. 28, February 18, 1942 pages 99-106.

- * Annual Report of the Smithsonian - 1945.
- * Science - R.E. Siedel December 11, 1943, pages 10-11.
- * New York Academy of Sciences - 1940-1950, 1967.
- * New York Times - September 10, 1953.
- * The Herald, Tijuana - January 5, 1958.
- * Los Angeles Times - November 22, 1931; December 27, 1931.
- * San Diego Evening Tribune - May 6, 1938; May 11, 1938.
- * San Diego Union - November 3, 1929; July 31, 1949.
- * Lee Foundation For Nutritional Research Report reprint #47
- * Journal of the Franklin Institute - February 1944 pages 103-129.

The articles created an optimism as mankind seemed headed toward getting the upper hand in the fight against disease. No one was more excited than members of the special medical committee established at the University of Southern California to evaluate Rife's work.

It was the findings of the members of this special committee who reported in 1940 that "Rife's discoveries represented an entirely new theory of the origin and cause of disease and the treatment results have been so unique and unbelievable that we may be able to eliminate the largest causes of death in the world".

When the facts regarding Rife's work were released, the economic realities of the medical drug, research, and petrochemical monopoly was threatened. It was too inexpensive, too effective. The technology could conceivably affect in an adverse way most of the businesses and professions dealing with pharmaceutical industry and drug related research.

Anything having a profoundly negative economic effect on such a large segment of the economy "could not be allowed to exist".

In their book, Lynes and Crane reported that Crane was told by Associated Press Science writer Howard Blakeslee that Dr. Morris Fishbein, the President who controlled the AMA for many years tried to buy out Rife's technology. When Rife refused, the suppression of this incredible technology began and a smear campaign launched to discredit, intimidate and threaten the parties involved.

Instruments were destroyed, the lab burned and records were stolen to insure the evidence would not survive. The AMA and Drug Interests tried to create a myth that Rife's research never happened and used the courts to insure Rife's work was stopped. Although they could not bring a conviction, it destroyed Rife personally and his work gradually came to an end.

According to T.E. Bearden, international authority on electromagnetics, "Rife revealed the direct connection between organized living energy forms and organized biological systems. He produced direct, economical electromagnetic solutions to dehabilitating disease. Rife's work presages what the future of mankind could have had . . . a future where most diseases were quickly and economically corrected. For his work he was ostracized, his findings though printed in reputable journals were discredited and ridiculed by the "Medical Cartel"."

In March of 1976, an article about Rife by journalist Christopher Bird appeared in the New Age Journal. The article generated a renewed interest in Rife and efforts were initiated to replicate the "Lost Technology".

A replica of the Rife instrument and the original schematic was obtained by a medical equipment electronics engineer. The engineer developed an updated device using patented transistors and integrated solid state circuitry instead of the electron vacuum tubes used in Rife's device.

The new frequency device called a Resonator was tested and researchers found that the immune system of the body appeared to be stimulated into action rather than the actual demise of the pathogens which occured as a result of the original frequency instrument. Initial clinical research reports indicate both the solid state and vacuum tube instruments to be equally effective although the actual mechanisms may differ.[3]

Under federal law the Resonator frequency instrument can only be used for investigational and educational purposes, to study and verify the work of other scientists such as Rife. As such the Resonator is considered an experimental research device. No claim can be made for the diagnosis or treatment of any disease.

The Resonator as an investigational tool is automated and requires no training beyond the instructions provided. A full 1 year warranty is included with purchase of the research instrument.

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EI	ear infections
EDEMA	
Ears -- ERN	rebuild nerves in ears
EARS 7	ear problems
Ear infection	
ELDERBERRY/PEPPERMINT	bronchial congestion and discomfort
ENDOCRINE 15	blood sugar problems - rebuilds whole endocrine system w/ focus on adrenal problems and blood sugar.
EMOTIONAL SHOCK	
EMURSIS	
EPILEPSEY	
EPSTEIN BARR	helps fight this problem - use with DISGO 3
EPITHILIOMIN	fights MT
EUGENOL	infections
D EYE	heal eyes
EYES 7	helps all eye problems
EYES - GLAUCOMA	
EYE SPECIAL	
E/V/A	escholtzia - valerian - aubpine
FEN	helps depress appetite for sugar and sweets

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GARLIC TINCTURE	
GARLIC CAYENNE TINCTURE	
G/P	germanium/platinum tincture -- helps build immune system
GINKO BILOBA	
GOUT 11	
HC 13	hormone corrective
H_2O_2 3%	food grade peroxide 3%
HAEMORROIDS	R/11 3C
HAEMORROIDS (rectal irritation)	
HEADACHE	
HEART 13	
HEMORROHAGE 10	
HEMOPHILLIA 1	
HEMOPHILLIA 2	
HERPEX TINCTURE	herpes problems
HYDROPIC REMEDY	fluid retention
IMMUNIZATIONS ---	set of five bottles for complete kit
BOTTLE #1	diptheria, pertussis, tetnus
BOTTLE #2	polio, small pox, typhoid, scarlet fever
BOTTLE #3	mumps, scarletina, chickenpox
BOTTLE #4	measles, black german red and yellow

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Formulations By:
Nutricion Labs & Dr. James Solomon
For Experimental Use Only

BOTTLE #5	meningococcus
INFLUENZA REMEDY	
INDEROL TINCTURE	
INSOMNIA #1	restless, overactive mind, can't relax
INSOMNIA #2	achey feeling can't sleep
INSULIN "NPH"	
INSULIN "R"	
INSULIN "C"	
INTERFERON TINCTURE	
IODINE ORGANIC	fucus
J/C/Y	jatoba--cecropia yua--helps weakness from illness; expectorant, strengthens respiratory system, strengthens and cleanses glands, removes muccous
JAUNDICE REMEDY	
K/B #13	kidney-bladder problems
KR	kidney repair
LMT	homeopathic antibiotic
L/G #1	liver/gallbladder treatment degenerative problems
L/G #3	liver/gallbladder treatment--hard liver
L/G #5	liver/gallbladder treatment--degenerative and hard liver
L/G #8	old liver problems
LAETRILE #3	homeopathic
A-LAX	adult laxative
C-LAX	children's laxative

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Formulations By:
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For Experimental Use Only

LEGS #3	restless legs -- cramping and pain
LITHO	all lithotropic (stone) problems-- Will need to drink 2-4 oz. apple juice 20 to 30 minutes after each dose
L/A	for digestion
LOBELIA	homeopathic vascular motor stimulant-- poison and toxin neutralizer
LUNGS #14	homeopathic formula for emphysema problems
LYMCO	lymph system cleanse and strengthener
LYMPH - NEW	homeopahtic tincture
MTT	bacteriacide -- helps with cysts and tumors related to bacterial infections
HM	homeopathic minerals
TM	trace minerals
MACULAR DEGENERATION	homeopathic remedy to correct problems in eyes
MENSTRUATION REMEDY	
MENOPAUSE	
MENIERS #15	ear noises--dizziness from inner ear infections
MIGRANE REMEDY	
MIGRANE AND NEURALGIS	
MONOSODIUM PHOSPHATE	homeopathic
MORNING SICKNESS	
MONE	chemotherapy neutralizer
MDD	marijuana and drug detoxifier
MND	marijuana neutralizer and detoxifier
MYCOCYDE I	infections

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Formulations By:
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MYCOCYDE II	infections
MYRRH-GOLDENSEAL PLUS	homeopathic tincture
MYASTENIA GRAVIS	
NFR	neutralize free radicals
RN #14	rebuild nerves
NAIL DISEASE	
NAUSEA REMEDY	
NERVOUS BREAKDOWN REMEDY	
NERVE AND INSOMNIA	
NERVE REMEDY	
NERVOUS EXHAUSTION REMEDY	
NERVOUS AGITATION REMEDY	
NERVOUS DISEASE REMEDY	
NEURASTHENIA, BRAIN FOG	
NERVOUSNESS AND HYSTERIA	
NERVOUS TENSION REMEDY	
OVER SENSITIVITY REMEDY	
PAIN EED	endorphin-enkelphin-dynorphine pain formula
PAIN--VISCARAL	
PAIN--TAP	transient aches and pains
PARKINSONS #12	
PERRIWINKLE	homeopathic tincture
POISON IVY ANTIDOTE	
PROSTATITIN	
POTASSIUM #33	

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Formulations By:
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For Experimental Use Only

QUININE SULPHATE	
QUEBRACHO #8	has potassium and other herbs to help lungs digitalis of the lungs
RANE	radiation neutralizer
RHFC	RH factor corrective
RECTAL IRRITATION	
REGENERATIVE	regeneration of body
RUSCUS ACULEATUS	circulation
SCALP & HAIR	
SCAR TISSUE #15	
SCHIZORPHRENIA	
SEPTIC CONDITIONS REMEDY	
SINUSTITIS REMEDY	
STIMULATING REMEDY	
SULPHUR	homeopathic tincture
SULPHUR-IODIDE	homeopathic tincture
SWEEDISH BITTERS	for all infections--body builder
TEGRETOL	homeopathic tincture
TEETH & GUMS	
TONSILS DISEASED REMEDY	
TOXEMIA--ANTIDOTE	
TOXEMIA #1	
TUSO #1	tumor solvent
TUSO #3	tumor solvent
USTELAGO	bleeding problems
V/A TINCTURE	homeopathic for cleaning out and strengthening the veins and arteries and rebuilding the veins and arteries

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Formulations By:
Nutricion Labs & Dr. James Solomon
For Experimental Use Only

V/P TINCTURE	vermacide -- gets rid of parasites -- helps with cysts and tumors related to viruses parasite problems
VIOLET--PARMA	
VIOLET--RICH	
VERICOSE VEINS	
VERTIGO REMEDY	
VALERIAN PLUS	
X-RAY REMEDY	
X-RAY DAMAGE TINCTURE	X-Ray and radiation neutralizer
YEAST #23 TINCTURE	fights yeast infections
Z TINCTURE	viricide--viral infections
#17 TINCTURE	used for degenerative problems helps dissolve cysts tumors and growths
#69 TINCTURE	
#81 TINCTURE	

SPECIALS

ANTIDOTE FOR MEASLES SHOT	
HOMEOPATHIC MOTRIN	anti inflammatory
LADY PINKHAM	
MALE HORMONIZER	
MAX EPA	homeopathic cleanse will not hurt pregnant women
MICRONASE	
MULTIPLE BIRTH	
MEMORY--WEAK	
MALARIA Prevent	

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Formulations By:
Nutricion Labs & Dr. James Solomon
For Experimental Use Only

MONTEZUMA'S REVENGE--Prevent	
PEMHIGUS VULGARIS	BULLOUS DISEASE use with BMR and other needed blood builders (yeast infection crossed with unknown #3 enters system on contaminated food--not inherited
OCCULOTROPHIN	
WEIGHT LOSS FORMULA E#1	
WEIGHT LOSS FORMULA E#2	
WELLNESS FORMULA	
WHITE WILLOW	
WHITE OAK BARK	
WITCH HAZAL	homeopathic
WOUND HEALING	

METABOLIC RESEARCH FOUNDATION
INTERNATIONAL OFFICE

DESCRIPTION

001 Emulsified A

Emulsified vitamins are absorbed faster than other dosage forms because the vitamins enter the circulatory system directly through the lymphatic duct. As a result, serum vitamin levels are higher. Each drop supplies 15,000 I.U. Vitamin A. All materials from natural sources.

002 B-Complex

A unique product containing all the essential B vitamins in a matrix scientifically compounded for the best total absorption. Each tablet contains: Folic Acid 400 mcg., Thiamine 30 mg., Riboflavin 60 mg., Niacin 50 mg., Vitamin B6 (Pyridoxine HCL) 60 mg., Vitamin B12 25 mcg., Pantothenic Acid 100 mg., Biotin 25 mcg., Choline Bitartrate 100 mg., Inositol 100 mg. and PABA 50 mg. (Hypoallergenic formula)

003 Vitamin C - 1,000 mg

Each tablet contains starch-free Vitamin C (ascorbic acid) 1,000 mg. from natural sources. (Hypoallergenic formula)

004 Calcium

Each tablet contains 745 mg. of microgranulated Calcium Orotate providing 85 mg. of elemental Calcium. (Hypoallergenic formula)

005 Iron Compound

Each tablet contains Iron (Ferrous Sulfate) 20 mg., Vitamin B-12 (Fermented Concentrate) 5 mcg., Copper (Organic Salt) 1 mg., Folic Acid 100 mcg., Vitamin C 50 mg., Liver (dried) 300 mg., Stomach Substance (For the intrinsic factor) 100 mg., (Vitamin C reduces the iron to FE++ for maximum absorption while stomach substance eliminates gastic irritation for use in dietary or nutritional anemias.

006 Multivitamineral - Trople granulated for Maximum Bio-availability

High potency multivitamineral tablet including vitamins A, D3, E, and B-Complex factors along with calcium, phosphorus and iron. Each tablet contains: Vitamin A (fish liver oil) 10,000 I.U., Vitamin D3 (Fish liver oil) 400 I.U., Vitamin E (D-alphs tocopheryl acid succinate) 200 I.U., Vitamin B1 (Thiamine) 3.75 mg., Vitamin B2 (riboflavin) 4.5 mg., Vitamin B6 (pyridoxine HCL) 5 mg., Vitamin B12 (cyanocobalamin) 5 mcg., Vitamin c (ascorbic acid) 200 mg., Pantothenic Acid (Calcium pantothenate) 30 mg., Folic Acid 400 mcg., Neacin 20 mg., Biotin 30 mcg., Calcium (bone meal) 75 mg., Phosphorus (bone meal) 33 mg., Iron (farrous fumarate) 6 mg., Iodine (kelp) 45 mcg., Manganese (Gluconate) 3 mg., Copper (Gluconate) 3 mg., Zinc (Gluconate) 5 mg., Kelp (Macrocystis pyrifera) 30 mg., Also contains lemon bioflavonoid complex 25 mg., PABA 7.5 mg., inositol, 15 mg., magnesium 5 mg (form magnesium oxide) potassium (form kelp) 3.7 mg., dried stomach substance 25 mg., liver substance, heart concentrate and lecithin. Free of corn, yeast, sugar, artificial color or flavor.

007 - Lithium

Each tablet contains 135 mg. of microgranulated Lithium orotate, providing 5.8 mg. of elemental lithium. (Hypoallergenic)

008 - Magnesium

Each tablet contains 775 mg. of microgranulated Magnesium orotate providing 56 mg. of elemental magnesium. (hypoallergenic)

009-Bone

Each tablet contains; Manganese Sulphate 250 mg. (elemental Manganese 80 mg.); Calcium Orotate 200 mg. (elemental calcium 22.6 mg.); Magnesium Orotate 200 mg., (elemental Magnesium 15 mg.; Vitamin c (Calcium Ascorbate) 50 mg., Vitamin c (Calcium Ascorbate) 50 mg..; Vitamin B-6 (Pyridoxine MCL) 50 mg.; Vitamin D2 (Ergocalciferol) 50 I.U. (Hypoallergenic).

010 - Potassium

Each tablet contains 300 mg microgranulated Pottassium Orotate providing 60 mg of elemental Potassium. (Hypoallergenic).

011 - Zinc

Each tablet contains 316 mg. of microgranulated Zinc Diorotate providing 55 mg. of lelmental zinc. (Hypeoallergenic).

012 - Digestive Aid

Two tablets contain Betaine Hydrochloride 106.0 mg. (Equivalent to 10 drops of dilute hydrochloric acid, USP), Pepsin USP 32.4 mg., Papain 64.8 mg., Mycozyme (Starch digestant) 64.8 mg., Ox bile 64.8 mg. This product is free of corn, yeast, sugar, artificial color or flavor.

013 - Pancreatic Enzymes

Each tablet contains Pancrelipase (Protease activity; 141.2 x NE: equivelent to 2 mg 3,000 x NE Trypsin) 43 mg., plus inositol 20 mg The tablets are sealed to prevent enzymatic activity. Free of corn, yeast, sugar, artificial color or flavor.

014 - Enzyme T (Total Blood Cleaner)

The result of two decades of experimentation by German and American scientists. An enteric coated proteolytic enzyme formula, containing Pancreatin 100 mg., Papain 60 mg., Bromelain

Chymotrypain 1 mg., and Kutin 50 mg.

015 - enzyme b (Bares Tumor)

The result of two decades of experimentation by German and American Scientists. An enteric coated proteolytic enzyme formula containing Papain 2.5 mg., Pancreas 2.0 mg., Thymus 1.0 mg.

016 - Enzyme W

The result of two decades of experimentation by German and American Scientists. Water soluble enzyme tablets. Each tablet supplies Papain 110 mg., Beef pancreatin 90 mg., Thymus concentrate 50 mg., Browelain 50 mg., Lipase 6 mg.

017 - Amino Acids

Contains L-Isoleucine, L-Liucine, L-Leucine, L-Lusine, L-Methoinine, L-Cystine, L-Phenylalaine, L-Tyrosions, L-Tryptophan, L-Valine, L-Threonine, L-Arginine, L-Alanine, L-Cysteine, L-Glutamine, L-Glycine, L-Histidine, L-Serine, L-Taurine, L-Aspartic Acid (by activity). (Hypoallergenic formula.

018 - Brain (Bovine source)

A dietary food concentrate (not an extract). Each tablet supplies 200 mg of raw brain concentrate. (Hypoallergenic formula)

019 - Adrenal (Bovine source)

Each tablet contains 200 mg. of whole adrenal gland (medulla and cortex) with choline bitartrate 100 mg., Vitamin B6 5 mg., Vitamin c 200 mg., Bioflavonoids 25 mg., and sea plant trace mineral concentrate 100 mg., with dessicated liver 10 mg. for support. Free of corn, yeast, sugar, artificial color or flavor.

020 - Duodenum (Bovine source)

Each tablet contains cold processed duodenal concentrate 500 mg. (Hypoallergenic formula)

021 - Gonadotrophin-M

A unique combination of gonadotropin potantiators including on a per-tablet basis, Natural orchic concentrate 200 mg., Natural spleen concentrate 100 mg., Thiamine 25 mg., L-Glutamic Acid 60 mg., Zinc 15 mg., Natural pituitary concentrate 20 mcg., Natural hypothalamus Concentrate 20 mcg. (Hypoallergenic Formula)

022 - Gonadotrophin - E

A multi-glandular, vitamin and mineral formula designed for the active woman. Each tablet supplies raw ovarian concentrate (not an extract) 50 mg., raw pituitary concentrate 12.5 mcg., Vitamin c 100 mg., Iron 20 mg.,Copper 1 mg. In a base of dried stomach and liver concentrate, for maximum absorption without gastric irritation. Free of corn,yeast, sugar, artificial color or flavor.

METABOLIC RESEARCH FOUNDATION
INTERNATIONAL OFFICE

023 - Heart (Bovine source)

Each tablet contains raw heart concentrate 200 mg., Magnesium (Magnesium Oxide) 30 mg., Manganese (Manganese Gluconate) 2 mg., Potassium (Potassium Chloride) 90 mg., (Hypoallergenic formula).

024 - Kidney (Bovine source)

A dietary food concentrate (not an extract). Each tablet supplies raw kidney concentrate 400 mg. (Hypoallergenic formula)

025 - Liver (Freeze Dried)(Bovine source)

A natural source of B-Complex vitamins.

026 - Spleen (Bovine source)

A dietary food concentrate (not an extract). Each tablet supplies raw spleen concentrate 454 mg. Excellent RNA-DNA supplement. (Hypoallergenic formula)

027 - Thymus (Bovine source)

A dietary food concentrate (not an extract). Each tablet supplies raw thymus concentrate 200 mg. Excellent RNA-DNA supplement. (Hypoallergenic formula).

028 - Selenium

A special formula containing 100 mcg. of selenium plus chromium in a kelp base. (Hypoallergenic formula)

029 - Sodium Alginate

An herbal detoxified, containing dietary fiber in the form of Sodium alginate 250 mg., and dehydrated celery leaf and stalk 250 mg. Improved for maximum absorption. (Hypoallergenic formula)

030 - S.O.D.

Each anti-oxidant tablet contains Superoxide Dismutase 3,000 Units/gm., Catalase 50,000 Units/gm., Glutathione *McCord-Eridovich Units of activity.

031 - H.F.1

An anti inflammatory homeopathic. It contains Apis mel 4x, Belladonna 4x, Mercur corr 5x, Barytamur 6x, Lachesis 12x and Phytolacca 6x.

032 - H.F. 11

An anti-inflammatory homeopathic. It contains Rhus tox 4x, Dulcamara 4x, Nux Vomica 4x, Causticum 6x, Barberis Vul 4x and Calcarea Phos 12x

033 - H.F. 30

An anti-inflammatory hemeopathic. it contains Strontium Salicylate 4x, Hexalethylenamine 4x, Colchinum 5x, Cimicifuga 3x and Franciscea Uniflora 5x.

034 - H.F. 46

An anti-inflammatory homeopathic. it contains Ferrum Phosph 12x, Lithius Carbonate 8x, Natrius Sulph 30x, Nux Vomica 12x, Rhododendron 6x and Spirea Ulmaria 8x.

035 - Trace Minerals

A homeopathic preparation of trace minerals including Calcium Carbonate, Magnesium (Hosphate, Silicea, Natrum Irradicum and Kale Irradicum.

036 - Thyroid

A homeopathic thyroid preparation.

E. F. SKILLING INC.
P.O. BOX 61
BUHL, IDAHO 83316

208-543-8547

1989 CATALOG

EXPERIMENTAL ELECTRONIC DEVICES

EFFECTIVE 1-1-89

E. F. SKILLING INC.
P. O. Box 61
Buhl, Idaho 83316

The present line of pulse generating equipment is designed and manufactured for research persons for investigation and educational study of pulse energy on plants, animals, and humans. This type of equipment is not intended for the specific treatment of any disease in animals or humans, but may be used for the study of the effects of pulse stimulation.

PLEASE NOTE

NO MEDICAL CLAIMS ARE MADE OR IMPLIED IN THE USE OF THESE DEVICES. FEDERAL LAW PROHIBITS THE USE OF THIS TYPE OF EQUIPMENT FOR THE TREATMENT OF DISEASE.

E. F. SKILLING INC.
P. O. Box 61
Buhl, Idaho 83316

WHAT IS A RESONATOR?

Resonance is the reinforcement or intensification of electrical vibrations. As an example, mount two tuning forks of the same pitch with the open ends facing each other. If one is struck with a soft mallet then quickly silenced by grasping the prongs with one hand, the other fork will be found to be sounding loudly enough to be heard over a large room. They come into sympathetic vibration—*resonance*—with one another.

Like the resonance of the tuning fork, all "matter" (molecules and atoms) in the universe is electrical and is vibrating at a specific vibration characteristic of the substance, producing minute oscillating currents. When an electrical signal is producing an oscillation and this energy strikes a molecule of matter that is tuned to the same frequency, it will cause the matter to oscillate in sympathetic vibration. If the electrical configuration of the matter is out of electrical balance (not at its natural frequency and intensity) we believe that the proper electrical oscillating signal will stimulate it to cause it to come into sympathetic vibration and be restored to its equilibrium or natural resonance.

Pioneers in experimentation with this theory using electrical oscillators—such as Dr. Albert Abrams (who may have been the first) in 1915, his protege Dr. Ruth Drown, Georges Lakhovsky, and many others who followed—were successful in experimental demonstrations with the principles of electrical resonance.

E. F. SKILLING INC.
P. O. Box 61
Buhl, Idaho 83316

E. F. Skilling Inc. has been involved in producing unique electronic pulse devices since 1960. The present line of pulse generating equipment is designed and manufactured for research persons for investigation and educational study of pulse energy on plants, animals, and humans. This type of equipment is not intended for the specific treatment of any disease in animals or humans, but may be used for the study of the effects of pulse stimulation.

Our equipment is provided with batteries for DC input power. The application and use of the electronic energy produced by this equipment must be developed by the user—whether a medical practitioner, veterinarian, or experimental research scientist. Our company only provides the hardware for research applications. We can design and fabricate "one-of-a-kind" electronic devices for specific interests.

Our company is a licensed medical equipment manufacturer holding FDA registration #3023460.

PLEASE NOTE

NO MEDICAL CLAIMS ARE MADE OR IMPLIED IN THE USE OF THESE DEVICES. FEDERAL LAW PROHIBITS THE USE OF THIS TYPE OF EQUIPMENT FOR THE TREATMENT OF DISEASE.

E. F. SKILLING INC.
P. O. Box 61
Buhl, Idaho 83316

TERMS AND CONDITIONS
EFFECTIVE 1-1-89

WARRANTY
If the Purchaser is not satisfied with the performance or quality of any of our products within the first thirty (30) days, Purchaser is allowed to return the item for a refund if the product is in like-new condition. *A minimum 10% fee will be charged if the product is not in like-new condition.* **This warranty does not apply to products #526-A and #524-B, or items not listed in our current catalog.**

All of our products have a full one year warranty. If any service is required, please contact our sales department for a return number and shipping address prior to shipping the item back for repairs. Return the item as instructed, prepaid, and we will, at our option, either repair or replace it.

If your order is damaged in shipment, contact the carrier at once. We are not responsible for products damaged or lost by the carrier.

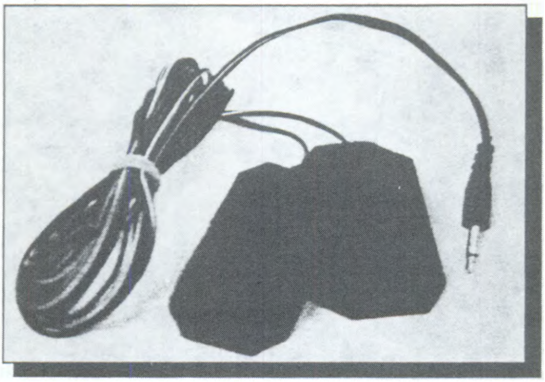
ORDERS FROM OUTSIDE THE UNITED STATES
We are happy to sell to customers in foreign countries. Remember, however, that you have to pay customs and import fees at your end.

PRICES
E. F. Skilling Inc. reserves the right to change prices without notice, to make changes and improvements in the products, or discontinue items at any time without obligation to make those changes to existing products.

SPECIAL ORDERS
TERMS: Payment in full with all special orders. Allow six to eight weeks (or more) for delivery depending on the time of the year and our work load at the time of the order. Add $4.50 to the order for shipping and handling charges. **ALL SALES ARE FINAL ON SPECIAL ORDERS; NO REFUNDS OR EXCHANGES ARE ALLOWED.** ***THERE WILL BE NO EXCEPTIONS TO THIS POLICY UNDER ANY CIRCUMSTANCES.***

E. F. SKILLING INC.
P. O. Box 61
Buhl, Idaho 83316

REPLACEMENT PADS



#506 – 1 1/2" x 2 1/2"
Standard Replacement Pads

#506A – 2 1/2" x 2 1/2"
Pro Replacement Pads

#506B – 5" x 5"
Super Pro Replacement Pads

E. F. SKILLING INC.
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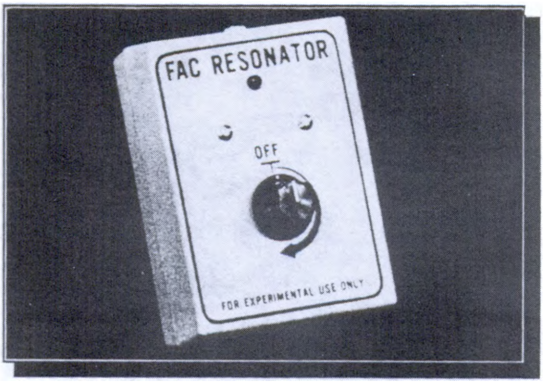
#507 FAC RESONATOR


FAC RESONATOR
OFF
FOR EXPERIMENTAL USE ONLY

This low frequency pulse rate generator is designed to be used by researchers in the study of the effects of magnetic phosphene in its relation to balancing the etheric field of the human or animal aura. Easy to use, with instructions included.

FOR RESEARCH STUDY PROGRAMS
OF VARYING PULSE RATES

E. F. SKILLING INC.
P. O. Box 61
Buhl, Idaho 83316

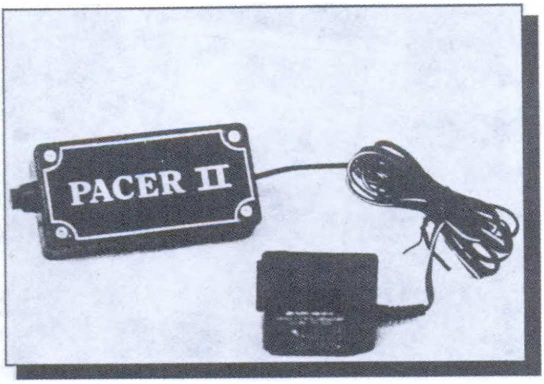
#504 LIL-RESONATOR

LIL-RESONATOR
FREQUENCY
OFF
FOR EXPERIMENTAL USE ONLY

A low cost unit with two control dials, rate and intensity, and improved linearity. A new high-impact plastic case features a battery compartment with sliding door on the rear of the unit, for ease of access. 1 Hz to 65 Hz frequency range, with a calibration mark on the dial at 7.83 (the Schuman earth resonance pulse rate). Single output through a 3.5mm mini plug for use of probes, pads, or other interface devices. Lil-Resonator comes complete with battery, instructions, and one set of flexible foam pads.

**FOR RESEARCH STUDY PROGRAMS
OF VARYING PULSE RATES**

#511-A PACER II



The design of the Pacer II is based on the theory of Dr. Ludwig of Germany that a magnetic field at the ELF Schuman earth frequency (7.83 Hz) may be beneficial in providing a shield against the influences of manmade electromagnetic fields such as are produced by computers, television, and other electronic devices that surround us in today's high technology world. Pacer II has increased pulse rate stability and digital pulse output with less magnetic power but increased effect. This unit has an AC-to-DC adapter so it can be operated 24 hours per day, eliminating the need for a battery. It radiates a field within a 2 to 3 foot radius which surrounds the user with a protective shield.

FOR EXPERIMENTAL USE ONLY

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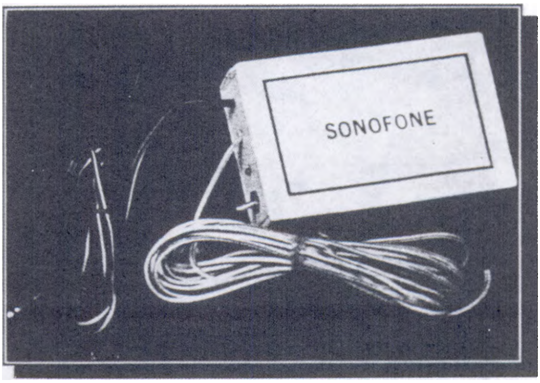
#523 SONOFONE



This experimental device is designed for the researcher in subliminal learning processes. It utilizes a carrier frequency just above the average hearing level of 20,000 Hertz, modulated by audible voice frequencies. Make your own subliminal tape message using your tape recorder or player. For example, record your own positive affirmations on a cassette tape, then it play back using the Sonofone. The transducer broadcasts an electrical field picked up by the subconscious of the listening individual. No consciously audible sound is heard when the unit is operating. Play the cassette tape through the Sonofone while reading, watching television, or otherwise relaxing.

FOR EXPERIMENTAL USE ONLY

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#511-B PACER III

The mini Pacer III uses the same electronic circuit that is in the Pacer II, but reduced in size to allow for easier carrying in a pocket or purse. It is in a new miniature plastic case, has a convenient belt clip, and uses a long-life 9-volt battery. The Pacer II provides the same protection from electromagnetic "smog" as the previous Pacer units.

FOR EXPERIMENTAL USE ONLY

E. F. SKILLING INC.
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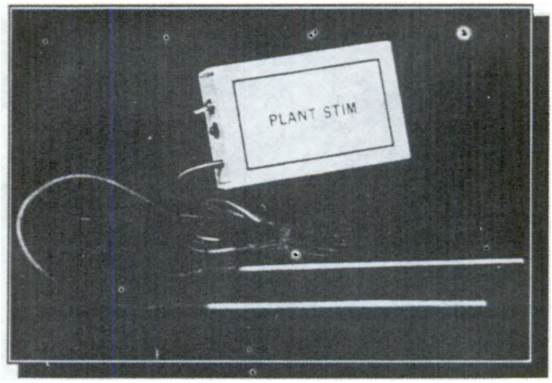
#524 PLANT STIM



The Plant Stim is an experimental device used to stimulate plant growth by inserting two probes into the soil in which the plant grows. Very small pulses operating at the earth Schuman resonance of 7.83 Hz will stimulate the plant to increase the growth rate. In many cases it will revive a dying plant.

FOR EXPERIMENTAL USE ONLY

E. F. SKILLING INC.
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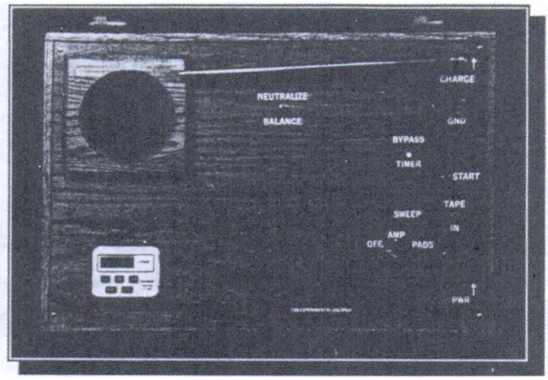
#526-A SWEEP III



The sweep III resonator is completely automatic, including pulse range and modulation. Harmonics of the top range can be found as high as 50 MHz. Input is provided for the analog signals from a cassette player/recorder which is converted to digital signals. This section of the Sweep III can be used to make subliminal output signals at 20,000 Hz, modulated by whatever information is recorded on the tape. A digital timer is provided. The unique input coil can be used to receive subtle energy signals. The unit comes with a nickel-cadmium rechargeable battery pack which provides 12-volt DC operating power.

See our instruction and information catalog for the Sweep III.

FOR EXPERIMENTAL USE ONLY

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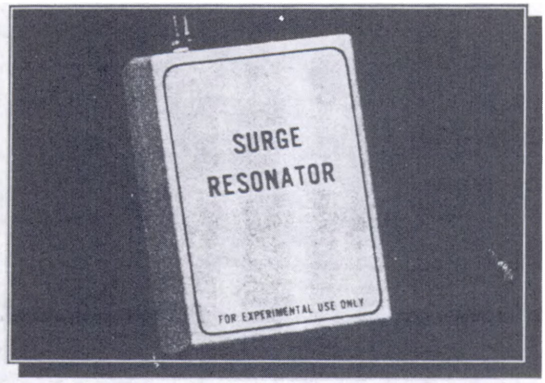
#529-A SURGE RESONATOR



A new experimental pulse generator utilizing a carrier frequency of 100 Hz with a surged low frequency modulation. Tests indicate that this modality produces a subtle energy effect that may balance the etheric body. Quartz crystal timing provides stability. The unit uses a long life 9-volt transistor-type alkaline battery, has a convenient belt clip and a 3.5mm output jack for connection to probes, pads, or other interface devices.

**FOR RESEARCH STUDY PROGRAMS
OF VARYING PULSE RATES**

E. F. SKILLING INC.
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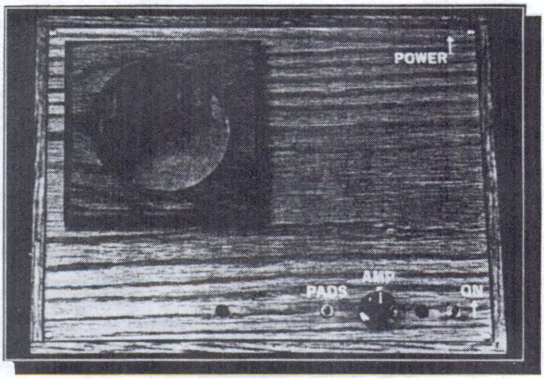
#526-B SWEEP IV-B



The Sweep IV-B is a fifth generation sweep generator utilizing the same sweep control used in the Sweep III, fully automatic in operation. The difference between the units is the elimination of the digital timer, antenna, ground lug, battery pack, neutralize balance switch, etc., to reduce the size of the package, resulting in a reduction of cost.

New for '89 is the option to have the Sonofone installed for a small fee. Please call our office regarding this option.

FOR EXPERIMENTAL USE ONLY

E. F. SKILLING INC.
P. O. Box 61
Buhl, Idaho 83316
(208) 543-8547

RETAIL PRICE LIST

PART #	DESCRIPTION	PRICE
504	LIL RESONATOR	$ 95.00
506	STANDARD PADS	$ 10.00
506-A	PRO PADS	$ 15.00
506-B	FOAM SUPER PRO PADS	$ 20.00
507	FAC RESONATOR	$ 125.00
511-A	PACER II	$ 95.00
511-B	PACER III	$ 95.00
523	SONOFONE	$ 250.00
524	PLANT STIM	$ 59.00
526-A	SWEEP III	$ 1600.00
526-B	SWEEP IV-B	$ 900.00
529-A	SURGE RESONATOR	$ 250.00
552	AC-DC ADAPTER	$ 10.95
554	OPTIONAL HEADSET	$ 35.00

E. F. SKILLING INC. RESERVES THE RIGHT TO CHANGE PRICES WITHOUT NOTICE.

E. F. SKILLING INC.
P. O. Box 61, Buhl, Idaho 83316
(208) 543-8547

PLEASE PRINT LEGIBLY

ORDER FORM

Name________________________________
Address______________________________
City ________________________________
State________________ Zip__________
Telephone Number________________________

SHIP TO:
Name________________________________
Address ______________________________
City_________________________________
State______________ Zip ___________

METHOD OF PAYMENT: Credit Card: ☐ VISA ☐ MasterCard **DATE:**__________________
☐ Check Credit Card No.:____________________ **Name on Card:**__________________
☐ C.O.D. Expiration Date:____/____ Authorization # __________ Ship Via:________________

QTY.	ITEM #	DESCRIPTION		PRICE EA.	EXTENSION

C.O.D. CHARGES	$ 2.50
HANDLING CHARGE	$ 4.50
SALES TAX (5% ID only)	
TOTAL	$

SHELDON S. KABAKER, M.D., F.A.C.S.

AESTHETIC FACIAL PLASTIC SURGERY MEDICAL CLINIC
3324 WEBSTER STREET, OAKLAND, CA 94609
(415) 451-1116 . FAX (415) 451-1426

October 17, 1991

Graydon Forrer
℅ Subcommittee on Regulations
B-63 Rayburn
Washington, D.C. 20515

Dear Mr. Forrer:

Enclosed are the promotional materials sent by the Paradise Pain Clinic. A similar package was received by my mother and brother, Hannah and Raymond Kabaker (3950 North Lakeshore Drive, Apt. #507B Chicago, Illinois 60613). In this packet are references made to Gary North, who obviously referred one other patient or the patient was referred by the same article seen in Gary North's newsletter.

My brother could not furnish me with a copy of the newsletter as he thinks he received it two or three years ago. In that newsletter, Gary North supposedly wrote that his wife or a relative was successfully treated for Epstein-Barr virus at the Paradise Pain Clinic, thereby giving a direct or indirect recommendation to his subscribers.

My major concern is that the testimonials that are sent out lead unsophisticated, elderly and impaired persons to have treatment for a wide variety of ailments through this electrical device that is promoted.

The investigative reporter in Las Vegas confirmed through her investigation that this group will treat any disease and they do it by having physicians or chiropractors write prescriptions for treatment.

When I called the Paradise Pain Clinic, stating that I wanted to know if they could treat my elderly mother for memory loss and hearing loss, they stated that they were a pain clinic and treated pain, but the side effects of treatment often improved a wide variety of ailments. They could only do treatment, however, on the prescription of a physician and referral from a physician, from anywhere in the country, would be acceptable. They sent me the enclosed promotional materials.

Accredited by
Accreditation Association for
Ambulatory Health Care, Inc. American Board of Otolaryngology . American Board of Cosmetic Surgery . American Board of Facial Plastic and Reconstructive Surgery

For Your Convenience

Listed below are several hotels or motels located near the Clinic. Patients are expected to make their own reservations.

Hotels and Motels

Fairfield Inn
3850 Paradise Road
Las Vegas, NV 89109
(702) 791-0899
(800) 228-2800

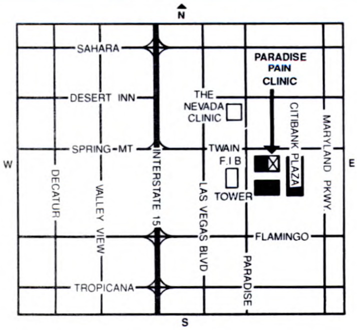
Best Western Mardi Gras, Inc.
3500 Paradise Road
Las Vegas, NV 89109
(702) 731-2020
(800) 634-6501

Sheffield Inn
3970 Paradise Road
Las Vegas, NV 89109
(702) 796-9000

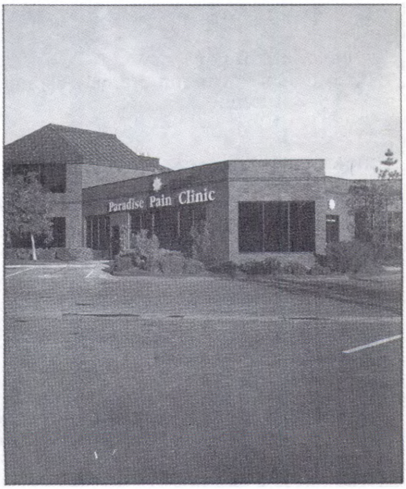
Quality Inn
377 E. Flamingo Road
Las Vegas, NV 89109
(702) 733-7777
(800) 228-5151

Restaurants:

There are five restaurants located within the complex.


N
SAHARA
PARADISE
PAIN
CLINIC
DESERT INN
THE
NEVADA
CLINIC
SPRING-MT
TWAIN
F.I.B
TOWER
CITIBANK PLAZA
MARYLAND PKWY
W
E
DECATUR
VALLEY VIEW
INTERSTATE 15
LAS VEGAS BLVD
FLAMINGO
PARADISE
TROPICANA
S

Paradise Pain Clinic


Paradise Pain Clinic

3900 Paradise Road, Suite F
Las Vegas, Nevada 89109
Telephone: (702) 733-1601
FAX: (702) 733-6479

Introduction

One of the most exciting developments in the field of medicine is the understanding and application of bio-electro therapy. Scientists and physicians have been accumulating knowledge about the electrical aspects of the human body for over 2,500 years.

Scribonius Surgus, a Greek physician to the Roman Emperor, used electric eels for therapy. In the 18th Century, Luigi Galvani investigated the effects of passing electrical current through muscular tissue. Building upon the work of his predecessors, Michael Faraday, a British physicist, demonstrated the therapeutic benefit of low-voltage current. By the first half of the 20th Century, electro-therapy was recognized as a safe and effective means of treatment.

In 1953, Dr. Iwao Yasuda, a Japanese orthopedic surgeon, discovered the piezoelectric nature of human bones. This information was utilized by Dr. Carl Brighton and his research colleagues at the University of Pennsylvania School of Medicine in the 1970's. Dr. Brighton implanted small electrodes on either side of non-union bone fractures, which had not responded to treatment in over two years. Out of the 210 patients treated, 85 percent demonstrated significant improvement of their condition in twelve weeks or less. Today, approximately one-third of all non-union fractures are treated in this manner in the United States.

By the late 1970's low-voltage current and electro-magnetic fields were being used to treat such conditions as pain (tendonitis, bursitis) and disorders of ligaments, bones and joints. Today, research is being conducted in the areas of bacterial inhibition, wound healing, mental illness and nerve tissue.

In the past, scientists and physicians have concentrated on the chemical characteristics of man. However, they are beginning to look beyond the chemistry of the cell and are now investigating the electrical polarities, fields and charges that make this chemistry work. Today's bio-electro therapy is the precursor to tomorrow's medicine.

Evans A. Rapsomanikis

The Inventor

Evans A. Rapsomanikis is the founder and research director of EBM Research Institute. For the last 34 years, he has pioneered the development of Bio-Morphic Energy, which is based on the science of bio-physics. In parallel with his continuous research in the bio-medical field, he held the position of Senior Research Specialist for Lockheed Corporation for twelve years and, prior to that, served with the Curtis-Wright Corporation (Electronics Division) in New Jersey, and with Pratt and Whitney Aircraft in Montreal, Canada.

Mr. Rapsomanikis developed the flight guidance system of the Lockheed L-1011 commercial aircraft and the anti-submarine warfare system for the S-3A Viking, a navy carrier based aircraft. He has spent many years of research in space electronics, specifically in the area of ionic radiation and its effects on the human body. This technology is an effective modality for the treatment of various pain causing degenerative diseases.

He earned his Bachelor's Degree in Mechanical/Electrical Engineering from Polytechnic University in Athens, Greece and his Master's Degree (MS EE) from the British Institute of Engineering Technology. Mr. Rapsomanikis has completed advance studies in physics and numerous medical courses at McGill University in Montreal, Canada.

Mr. Rapsomanikis is the author of more than 20 technical papers on space and anti-submarine warfare electronic systems. He is also the author of two technical books which are used as training manuals by the U.S. Navy.

Evans A. Rapsomanikis is a member of the following societies: Science and Engineering Council of Santa Barbara, Sigma Xi Scientific Research Society. The International Academy of Energy and Medicine, and the New York Academy of Sciences. He is recognized by Who's Who in California Historical Society.

How the technology works

One of the primary concepts behind this technology is the fact that the human body is self-sufficient. It contains heating, ventilating and air conditioning systems that maintain the body at a near constant temperature. There is also a sophisticated plumbing system which moves vast quantities of body fluids, filters them and eliminates the wastes and toxins. The body's structural system holds everything together and the musculoskeletal system enables us to perform complex movements. The defense (immune) system prevents invasion of the body by microorganisms and germs (such as viruses). A sophisticated computer/memory system allows us to accumulate knowledge and, at the same time, monitor and regulate all the other sub-systems. This function is of prime importance in the treatment of painful disorders and diseases.

The body is capable of self-repair provided that two conditions are met. First, it must have the proper nutrients necessary to initiate chemical reactions. Second, it also needs the correct monitoring and feedback signals to direct the chemistry. The failure of either of these functions results in a "breakdown" of the body's systems. When this occurs, the affected part of the body sends a distress (pain) signal to the brain. That signal contains information regarding the exact nature of the problem. The brain reacts by transmitting a specific repair program to the problem area. All damage and repair programs, regardless of the nature and location, use the same communications language. That language is electromagnetic in nature.

Pain is a symptom of a breakdown in the body's natural defenses. It seems that the Bio-Ionic System at our pain relief centers addresses the cause of the pain and helps the body to heal itself. It is not meant to be a cure for disease, but it has proved to be better than 80 percent effective in long-term elimination of pain associated with illness and injuries.

Our clinics are professionally staffed Bio-Physical Therapy Centers. Bio-Ionic Therapy is proven safe and it has helped many people where drugs and medications have failed.

Bio-Ionic System (BIS)

Because the body utilizes electromagnetic energy, it is possible to enhance the body's ability to repair itself. The Bio-Ionic System (BIS) device allows the body to draw the energy needed to carry out these repairs. The BIS is registered with the FDA and currently is in use at the Monrovia Center for Health Care and at the Company's headquarters in Ontario, California. It has been in use since the early 1970's and has proven its effectiveness in the treatment of chronic pain. Paradise Pain Clinic utilizes this device for the treatment of pain.

The treatment involves two steps. First, the source of the pain is determined. Then, therapy is administered with the BIS. Free electrons are released into the body at a controlled rate and intensity. These electrons are directly incorporated into the cells and provide the vital energy needed to restore normal cellular function. The program is continuously monitored and altered by a bio-feedback circuit which responds to cellular electron saturation. A truly holistic device, the BIS, treats the entire body, as well as the problem areas, and has no unwanted side effects.

The BIS uses adhesive conducting pads which contact the skin surface of the patient. The skin is never punctured. The technician places the pads according to the schematic diagram provided by the Director. The average treatment time is three hours. However, the number of treatments will vary, depending on the severity of the disorder. The Director also determines the necessary level or energy required for the treatment. Frequency and other electrical characteristics are pre-set into the device.

For Your Comfort

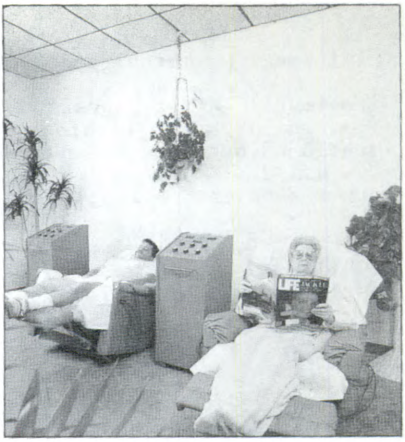
No Smoking is permitted in the clinic.

Please wear loose, comfortable clothing (preferably two-piece outfits). This will facilitate the treatment. Women: no nylons, jump suits or one-piece dresses.

Please refrain from using any fragrances, hair spray or colognes since some patients are allergic to chemicals and may become ill. Do not apply lotion to your body prior to your visit, as this inhibits effective treatment.

Unless otherwise directed, please eat prior to your appointment to prevent hunger. You may wish to bring a snack, but eating should be light. Ingested food will absorb some of the energy during treatment and may slow your progress. Do not drink excessive amounts of liquids before your treatment; bathroom visits will waste your treatment time.

You may wish to bring preferred reading materials, knitting or radio headphones to occupy your time during treatment. Some reading material is available at the clinic.



For Your Information

Hours:

Our business hours are 8:00 a.m. to 6:00 p.m., Monday through Friday, and from 9:00 a.m. to 12:00 noon on Saturday. During evenings and weekends, our answering service will take messages.

Appointments:

Several daily shifts have been scheduled beginning at 8:00 a.m.

If for any reason you are unable to keep your appointment, please advise the clinic at least 24 hours in advance or charges may be incurred.

Patients should arrive at least ten minutes before their scheduled time to be prepared for treatment. Patients who arrive late will lose valuable treatment time.

Billing:

All accounts must be paid in full at the end of each treatment unless other arrangements have been made in advance.

Insurance:

Paradise Pain Clinic cannot bill your insurance carrier. However, a Super-Bill will be provided to expedite your reimbursement.

Last week, my mother and brother were scheduled to fly to Las Vegas so that my mother might have two weeks of treatment. After a great deal of discussion, I persuaded them not to go. Therefore, I can only report the above-mentioned occurrences and, as of this time, at least have avoided involving my mother and brother in what I feel are fraudulent medical practices.

I would be glad to discuss this information with you further.

Sincerely,

Sheldon S. Kabaker, M.D.

SSK:ksw
Encl.

P.S. My mother is 87 years old and in reasonable health for her age. She has problems with hearing loss and memory loss which were conditions for treatment by the Paradise Pain Clinic.

REFERRAL

TO: PARADISE PAIN CLINIC

Please treat with the BIS-II device the following patient:

Name: ____

Address: ____

____

Reason for Referral: ______________________________

____

COMMENTS: ____

____

DIAGNOSIS: ____

____

Referring Physician: ______________________________

Address: ____

____

License Number: ____________________

____
Signature

PATIENT INFORMATION

Name____Age__________

Home Address__________________________________Phone_________

Local Address_________________________________Phone_________

Social Security #______________Driver's License #________________

EMPLOYER___________________________________Phone__________________

Address____

SPOUSE (or Parent)_______________________________Phone___________

Address____

Social Security # ______________Driver's License # ______________

Employer_____________________Address______________________________

IN CASE OF EMERGENCY, NOTIFY: ___________________________________

Address____Phone______________

REFERRING PHYSICIAN___________________________Phone______________

Who first told you about BioPhysical Pain Centers?

____

BIO8

Patient____Date______________

PAIN QUESTIONAIRRE

I. Location of pain (List most severe pain first; rate pain level on a scale of 1 to 10 with 10 being worst pain)

____

____

____

____

____

Does the pain go anywhere? YES NO

Describe ____

____

____

II. Check the follow statements which describe your pain:

______ Pain present at all times

______ Sometimes pain-free How long?__________________

Character of pain

______ Sharp

______ Dull

______ Cramping

Like electric shock ______

Burning ______

Numbness/tingling ______

Other (describe) ____

III. When pain becomes most severe, what do you do?

______ Sit down

______ Lie down

______ Use heat

______ Use ice

Massage ______

Traction ______

Ultrasound ______

Pain medication ______

IV. How long each day (other than normal sleeping time) must you spend in bed or reclining? ________________________________

How long can you:

Sit ______ hours/minutes

Stand ______ hours/minutes

How far can you walk ______ blocks/miles

How long does it tke you? ______ hours/minutes

V. List ALL medications you are presently taking:

____

____

____

Circle medications you have used in the past and gauge results (Good, Fair, No Relief):

______ Aspirin
______ Empirin/Codeine
______ Tylenol/Codeine
______ Darvon Compound
______ Darvocet N
______ Percodan
______ Demerol
______ Tolectin
______ Prednisone
______ Cortisone

______ Norgesic
______ Flexaril
______ Robaxin
______ Clinoril
______ Meclomen
______ Motrin
______ Naprosyn
______ Feldene

Other ____

BIO7

PARADISE PAIN CLINIC
3900 Paradise Road, Suite F
Las Vegas, NV 89109

INFORMED CONSENT FOR BIOPHYSICAL PAIN THERAPY

Patient______________________________________Phone______________

Address____

Referring Physician____

I understand that Paradise Pain Clinic, a BioPhysical Therapy Center, utilizes the Bio-Ionic System Device for the treatment of pain.

I have been advised that side effects are beneficial except minor skin irritation which may occur.

I acknowledge that no claims or guarantees have been made to me regarding the result of this treatment.

My signature attests that I am not pregnant, and do not have a cardiac Pacemaker, other electronic transplant, metal implant or other artificial device in my body (if any such condition exists, refer to specific waiver attached hereto).

As required, I am presently under the care of a doctor and I herewith present a diagnosis and referral.

By contract of my signature, I acknowledge that I have read and understand the foregoing, have been fully advised regarding biophysical therapy and possible known side effects and, hereby request and grant consent for biophysical therapy for pain.

____
Patient or Authorized Representative (Relationship) Date

____
Witness Date

BIO6

PARADISE PAIN CLINIC
3900 Paradise Road
Las Vegas, NV 89109

I, ______________________________________, Social Security Number ______-_____-_______, hereby acknowledge by this statement that I have been fully informed that the pain therapy provided at the Paradise Pain Clinic, on or after this date, may not be considered "reasonable and customary" by health insurance providers. I understand Medicare will not recognize such services.

I agree to pay Paradise Pain Clinic for all services at the time rendered. In turn, I will be provided with proper forms which I may submit to my insurance carrier for reimbursement.

____

Patient signature Date

PPC2

FAMILY AND PERSONAL HEALTH HISTORY

Note: Please complete all information on this record. All information is treated in confidence and will not be released unless you grant permission.

Name ______________________ Age ______ Birthdate ______________ Today's Date ______________

Occupation ______________ Last Physical Examination Date ______________ Daytime Phone ______________

FAMILY RECORD Check (✓) condition(s) and relationship of any blood relative who has or has had any of the conditions listed below.	YES	NO	FATHER	MOTHER	BROTHER	SISTER	SON	DAUGHTER
Alcoholism								
Allergies								
Anemia								
Arthritis								
Asthma								
Birth Defects								
Bleeding Tendency								
Cancer								
Colitis								
Congenital Heart								
Diabetes								
Emphysema								
Epilepsy								
Glaucoma								
Goiter								
Hay Fever								
Heart Attack								
Heart Disease								
High Blood Pressure								
Kidney Disease								
Leukemia								
Liver Disease								
Mental Illness								
Migraine								
Nervous Breakdown								
Obesity								
Rheumatism								
Rheumatic Fever								
Sickle-Cell Anemia								
Stomach Ulcer								
Stroke								
Suicide								
Tuberculosis								

FAMILY MEMBERS						
Living					**Deceased**	
	AGE	Health ✓ Good	✓ Fair	✓ Poor	DEATH AGE	Cause of Death
Husband						
Wife						
Mother						
Father						
Brother(s)						
1.						
2.						
3.						
4.						
5.						
Sister(s)						
1.						
2.						
3.						
4.						
5.						
Son(s)						
1.						
2.						
3.						
4.						
5.						
Daughter(s)						
1.						
2.						
3.						
4.						
5.						

Doctor's Use Only — Summary

Form 1832 © 1982 SYCOM Madison, WI Printed in U.S.A.

PERSONAL HISTORY

Describe your present medical symptoms

OPERATIONS	✓ Yes	✓ No	Date	[illegible]	✓ Yes	✓ No	Date
Tonsils				Small Pox			
Appendix				Tetanus			
Gall Bladder				Polio Shots			
Stomach				Polio Oral			
Small Intestine				Measles			
Kidney				Influenza			
Colon				German Measles			
Thyroid				Other - If yes, what:			
Hernia							
Breast (woman)				[illegible]			
Uterus (woman)				Eye Glasses			
Ovaries (woman)				Contact Lenses			
Prostate (man)				Hearing Aid			
Other - If yes, what:				Dentures			
				Partial Dentures			
X-RAYS				Neck Brace			
Back				Back Brace			
Chest				Other Brace			
Colon				Artificial Limb			
Extremities				Artificial Eye			
Gall Bladder				Truss			
Kidney				Pacemaker			
Stomach				I.U.D.			
Treatments				Diaphragm			
Other - If yes, what:				Orthodontic Appliance			
				Other - If yes, what:			
MEDICATIONS							
Insulin				[illegible]			
Cortisone				Penicillin			
Thyroid Medicine				Sulfa			
Blood Pressure Medicine				Aspirin			
Tranquilizers				Bufferin			
Sedatives				Foods			
Hormones				Fluids			
Birth Control Pills				Dust			
Valium				Fabric			
Digitalis				Metals			
Other - If yes, what:				Vitamins			
				Nail Polish			
Do you: If yes, daily consumption				Cosmetics			
Smoke Pkgs.				Lotions			
Drink Coffee Cups				Other - If yes, what:			
Beer ozs.							
Hard Liquor ozs.							
Have you been hospitalized?							
If yes, for what							

Doctor's Use Only — Summary

STUDY OF SYSTEMS

Check (✓) either yes or no for each item except where applies to only male or female

	Conditions	✓ Yes	✓ No		Conditions	✓ Yes	✓ No		Conditions	✓ Yes	✓ No
GENERAL	Fever				Stiffness				Is Your Life:		
	Chills				Swelling				Satisfactory		
	Bruise Easily				Lumps				Boring		
	Swollen Glands				Other*				Demanding		
	Loss of Memory			GASTROINTESTINAL	Appetite Poor				Unsatisfactory		
	General Weakness				Indigestion/Heartburn				Is There Worry Over:		
	Aches/Pains				Nausea				Home Life		
	Double Vision				Vomiting Blood				Marriage		
	Light Flashes				Abdominal Pain or Cramps				Job		
	Blurred Vision w/o Glasses				Abdominal Tension				Children		
	Halos Around Lights				Diarrhea				Money		
	Eye Pains				Constipation				Do You:		
	Ear Pains				Bowel Habit Changes				Often Feel Depressed		
	Ear Drainage				Rectum Blood Passage				Have Irrational Fears		
	Buzzing/Ringing in Ears				Black Tar-Type Bowel Movements				Feel Upset		
	Nosebleeds				Other*				Feel Things Often Go Wrong		
	Sinus Problems								Feel Shy		
	Swallowing Problems				Up Nights to Urinate				Cry Easily		
	Deafness				Blood in Urine				Feel Inferior		
	Mouth, Tooth or Tongue Problems				Burning or Pain While Urinating				Have You:		
	Persistent Hoarseness				Problem Passing Urine				Attempted Suicide		
	Severe Headaches				Trouble Controlling Urine				Seriously Considered Suicide		
	Other*				Other*			MAN GENITALIA	Lump in Testicles		
SKIN	Rash			NEUROMUSC	Leg or Arm Weakness				Penis Discharge		
	Changing Moles				Balance Problems				Breast Lump		
	Pigmentation				Dizziness				Sore on Penis		
	Other Skin Problems*				Fainting Spells				Erection Difficulties		
	Irregular Heartbeat				Speech Problems				Other*		
	Shortness of Breath				Other*				Breast Lump		
	Low Exercise Tolerance				Joint Pains				Nipple Discharge		
	Heart Flutters				Joint Swelling				Vaginal Discharge		
	Chest Pains				Muscle Strength Loss				Non-Period Bleeding/Spotting		
	Frequent Coughs				Muscle Lump or Swelling				Hot Flashes		
	Cough up of Blood				Lump on Bone				Pain with Intercourse		
	Wheezing				Pains in Back				Possibly Pregnant		
	Night Sweats				Other*				Change in Periods		
	Swollen Ankles			ENDOCRINE	Constant Thirst				Pain Other Than With Periods		
	Cramps in Legs				Most Always Cold				Other*		
	Other*				Too Warm Most Times						
					Very Sluggish or Tired						
					Jumpy/Nervous						

Explain Other*

Doctor's Use Only — Summary

PAST AND PRESENT MEDICAL PROBLEMS

Check (✓) all items either yes or no and give approximate date if past.	No	Yes Now	Yes Past	If Past Date
Asthma				
Abnormal Chest X-Ray				
Abnormal Electrocardiogram				
Angina				
Abnormal Stomach X-Ray				
Anemia (Type)				
Arthritis				
Blindness Either Eye				
Broken Bones				
Cataracts				
Chronic Bronchitis				
Cirrhosis of Liver				
Colon or Bowel Trouble				
Deafness				
Dysentery				
Diabetes				
Ear Infections				
Emphysema				
Enlarged Heart				
Glaucoma				
Gall Stones				
Gout				
Goiter				
Gonorrhea				
Hay Fever				
Heart Murmur as Adult				
Heart Attack				
High Blood Pressure				
Hepatitis				
Hemorrhoids				
Kidney Infection				
Kidney Stones				
Nervous Breakdown				
Poor Blood Clotting				
Polio				
Phlebitis				
Rheumatic Fever				
Rectal Trouble				
Recurrent Boils				
Stroke				

Check (✓) all items either yes or no and give approximate date if past.	No	Yes Now	Yes Past	If Past Date
Stomach or Duodenal Ulcer				
Syphilis				
Skin Disease				
Serious Depression				
Serious Emotional Problems				
Tuberculosis				
Thyroid (overactive)				
Thyroid (underactive)				
Varicose Veins				
Man				
Prostate Problems				
Woman				
Menstrual Difficulties				
Cystitis				
Mastitis				
Ovarian Cyst				
Breast Cancer				
Other Breast Disease*				
Other Gynecological Problems*				
Still Menstruating				

Age Periods Started ______________

Age Periods Stopped ______________

Why Periods Stopped ______________

Number of Pregnancies ______________

Number of Children ______________

Number of Miscarriages ______________

*Explain:

Man and Woman describe any unlisted illnesses you have had:

Doctor's Use Only — Summary

Paradise Pain Clinic
3900 Paradise Road, Suite "F"
Las Vegas, Nevada 89109
Telephone: (702) 733-1601
Fax: (702) 733-6479

THE TREATMENT

Upon arrival at the Paradise Pain Clinic, patients are given a systemic evaluation by the Director and are introduced to the treatment procedure.

This three-hour treatment is administered in private rooms individually decorated for comfort and quietude. Following precise instructions from the Director, technicians specifically apply non-intrusive electrodes to the patient's area of pain. These electrodes are unobstructive and no pain or discomfort is experienced during treatment.

While resting in recliner chairs, patients are free to sleep, read, listen to music, or just rest, as treatment is relaxing and restorative. Throughout this period, patients are monitored and checked by a thoroughly trained technician in the use and application of the BIS.

Any need the patient may have is accommodated. Technicians are easily summoned by private intercoms located next to the patients.

Healing is comprehensive and holistically accomplished. Support for the sophisticated curative system found within the body itself is our primary concern. Every effort is made to induce healing and relieve pain within the body.

From our uniquely designed rooms, to the personalized treatment, the Paradise Pain Clinic has been especially established for the relief of pain.

Kyttaron Energy Corporation

THE BIO-IONIC SYSTEM DEVICE (BIS-II)

One of the most exciting developments in the field of the healing arts is the final maturing of electro-medicine or electro-biotic therapy.

For at least 2500 years physicians have been accumulating knowledge about the electrical characteristics of the human body. Scribonius Surgus, a Greek physician to the Roman Emperor, used electric eels for therapy. Luigi Galvani, an 18th Century Italian scientist, investigated the effects of passing electrical current through muscular tissue. British physicist, Michael Faraday, established the fact that the current of electricity could produce measurable therapeutic benefits.

By the end of the 19th Century, a number of electrical devices were being used for both pain and healing in connection with a wide variety of human disorders. But, largely due to the primitive state of technology, most of these devices were marginally successful at best and, in some cases, even harmful. By the first half of the 20th Century, however, knowledge had advanced to the point where electro-therapy was recognized as both safe and effective when properly applied, and diplomas in medical electricity were being offered by numerous universities.

Most of the real advances, however, have been made in the relatively recent past. The BIO-IONIC system, which is used by the Paradise pain clinic and other pain clinics, was developed by Evans A. Rapsomanikis. It was completed and has been in use since 1969. Literally hundreds of persons have been treated with this device for pain. It has been proven that patients undergoing therapy with the BIS-II received a better than an 80 percent success rate in the relief of pain, without a single complaint.

The application of such therapy provides long lasting pain relief with no unwanted sequelae. The patient relaxes in comfortable surroundings under the direct care of qualified personnel, while the body performs its own natural healing functions.

KYTTARON ENERGY CORPORATION

In primitive times, illness was treated mystically by incantation and spirits. This was followed by centuries of experimentation with exotic plants and roots, leading to the herbal treatment of diseases with the arrival of scientific inquiry, we began the physical treatment of the body by repairing wounds and setting bones. The fourth stage came with the development of drugs and the chemical treatment of disease.

The fifth stage arrived with the rediscovery that nature produces her own healing chemicals, and this led, partially to a better understanding of ancient herbology, but mostly to the new concept of nutritional therapy.

Now we are entering into the sixth and perhaps the final stage in this progression of knowledge. With the realization that almost everything the body is and does involves electrons at the atomic and molecular level — that includes the action of drugs and nutrients — scientists are exploring the electron treatment of human disorders.

Most of the real advances, however, have been made in the relatively recent past. The Bio-Ionic System, which is used by the Paradise Pain Clinic and other bio-physical therapy centers, was developed by Evans A. Rapsomanikis. It was completed and it has been in use since 1969, and its performance is far beyond any imagination.

Because the body utilizes electro-magnetic energy, it is possible to enhance the body's ability to repair itself. The Bio-Ionic System (BIS) device allows the body to draw the energy needed to carry out these repairs. The BIS is registered with the FDA and currently is in use at the Monrovia Center for Health Care and at the company's Bio-Physical Therapy Centers in California.

The treatment involves two steps. First, the source of the pain is determined. Then, therapy is administered with the BIS. Free electrons are released into the body at a controlled rate and intensity. These electrons are directly incorporated into the cells and provide the vital energy needed to restore normal cellular function. The program is continuously monitored and altered by a bio-feedback circuit which responds to cellular electron saturation. A truly holistic device, the BIS treats the entire body, as well as the problem areas, and has no unwanted side effects.

Pain is a symptom of a breakdown in the body's natural defenses. It seems that the Bio-Ionic System at our pain relief centers addresses the cause of the pain and helps the body to heal itself. It is not meant to be a cure for disease, but it has proved to be better than 80 percent effective in long-term elimination of pain associated with illness and injuries.

Our clinics are professionally staffed Bio-Physical Therapy Centers. We work with your doctor to provide the highest level of care and comfort. Bio-Ionic therapy is proven safe and it has helped many people where drugs and medications have failed.

For additional information, please call:

Paradise Pain Clinic
3900 Paradise Road, Suite F
Las Vegas, NV 89109
Tel. (702) 733-1601
Fax (702) 733-6479

Bio-Physical Therapy Center
305 Sacramento Place
Ontario, CA 91764
Tel. (714) 983-2991
Fax (714) 983-2108

11584 Fremont St.
Yucaipa, CA 02300
11/27/90

Mr. Evans Rapsomanikis
3900 Paradise Road, Suite F
Los Vegas, Nevada 89l09

Dear Evans:

I apologize for being so slow in getting this letter to you. It is very hard to express to you the appreciation I feel for the help I have received from the treatments on the BIS-II. I thank God every day for leading us to know of you and the technology you have developed to bring relief and healing to mankind from so many of the diseases and aches and pains from which we all suffer at various times in our lives.

I have always had excellent health, which is certainly one of my greatest blessings. However, in 1976 I contracted Guillain Barre', and during the course of this illness I became paralyzed--face, arms, and legs--everything but my chest (for which I was most grateful). Being the debilitating disease it is, my recovery occupied a three year period. After this, the one reminder of this traumatic experience that remained was the paralysis of the right side of my face, which never left, even though various modes of treatment were utilized.

The other area of discomfort I had was degenerative arthritis of the spine, especially severe in the sacro-iliac area, as well as at the base of each thumb. The only treatment offered to me by medical doctors was to take cortisone injections or just take plenty of aspirin, which I did not like to do. This problem had been with me for 30 years, and was getting worse with the years.

When we first came to the Kyttaron Pain Clinic in Agoura Hills, I was told that your machines could most likely help the arthritic conditions I described. I proceeded to take the treatments, and since my back was especially acute at that time, I did feel relief from the back pain after the first treatment. We continued for a two week period to treat the back and the joints of both thumbs.

At one time I did mention the residual paralysis of the right side of my face, and was told it could possibly be helped by the treatments. However, I felt the possibility was quite remote, so thought no more about this area of concern.

After several more series of treatments, one day I discovered that the muscles on the right side of my face were beginning to function normally again! I can't tell you how excited I was to make this discovery. A one-sided smile is not normal or pleasant to give or receive! Besides this, my arthritis was showing continual improvement. While not totally free of pain, it would disappear for long intervals, and if pain would recur, it would be gone by the next day. After another series of treatments, I became virtually pain free from the arthritis. This lasted for approximately one month, until I had to become involved in a moving project. I tried to be very careful about lifting, bending or twisting, but it was virtually impossible not to do a good many things I knew I should not be doing. During this period of time (two months), I would be ever so sore with severely aching muscles and back at night when I would go to bed, but by morning it would be all gone and I was all right again. Somehow it would regenerate and heal itself, and I can say that, for the most part, now I am pain free and feel great, in spite of that difficult two month period of moving. Had I not had the treatments, I am sure (judging from experience of the past) my back would have totally given out.

As far as I am concerned, this machine has given me a new lease on life, and I am most grateful to you and to God for making this available for our use.

As you know, my husband's story is another series of miracles. Having had a heart attack in 1982 (and numerous cardiac arrests since that time), his course of recovery from the original attack has been a stormy one. For those eight years he had a continual problem with arrhythmia. His EKGs were bizarre. I can say that the effects on him have been miraculous, and it has been exciting to see the improvement in his condition. His EKGs now show a regularity that was not seen for eight years. Since he is a physician, he wants to write you when all the data has been brought together to give the documentation for the improvement we have witnessed.

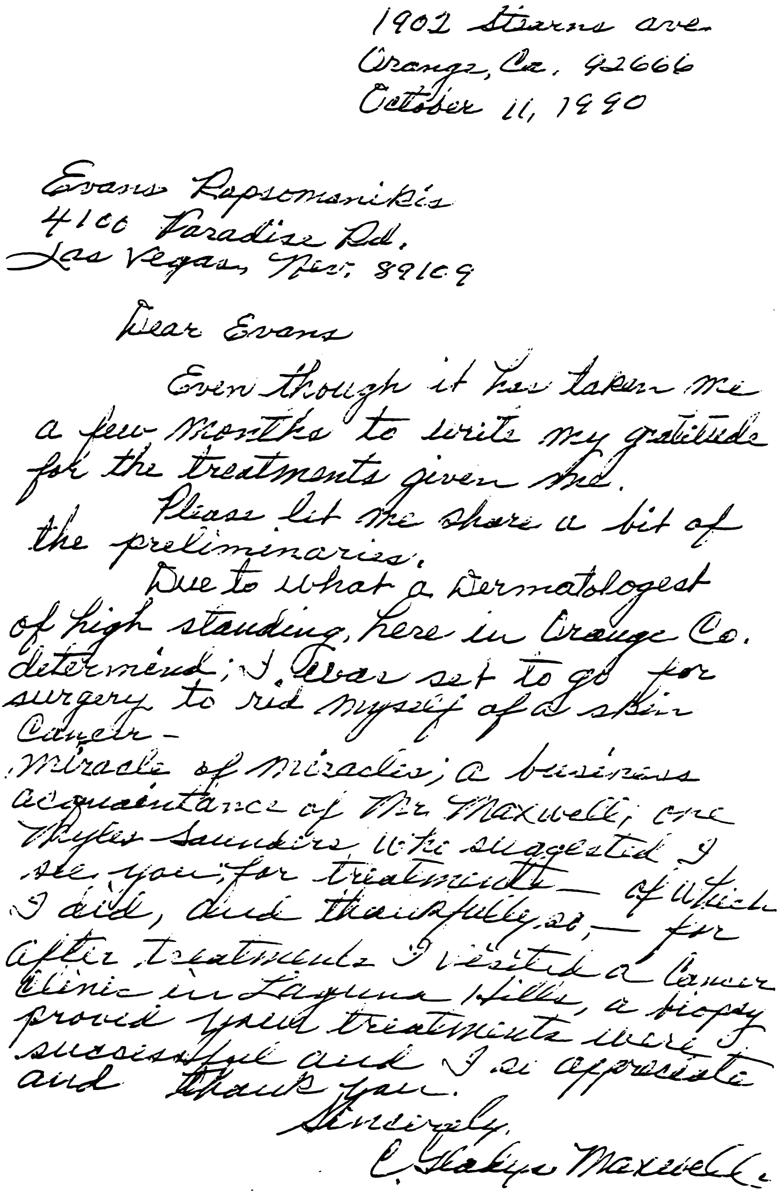
This letter would not be complete without a word of thanks and commendation for those who ministered so faithfully to our needs--Shirley and Dr. Nick. Their help and encouragement made our time spent there most pleasant and profitable. It is so rewarding to meet people who are willing to go beyond the call of duty to help others, and we want you to know how grateful we are to each of you for the benefits received from the treatments on the BIS-II. Many many thanks, and may God continue to richly bless you.

Kindest regards,

Elaine

Elaine M. Denmark

ed



1902 Stearns ave.
Orange, Ca. 92666
October 11, 1990

Evans Rapsomanikis
4100 Paradise Rd.
Las Vegas, Nev. 89109

Dear Evans

Even though it has taken me a few months to write my gratitude for the treatments given me.

Please let me share a bit of the preliminaries.

Due to what a Dermatologest of high standing, here in Orange Co. determind; I was set to go for surgery to rid myself of a skin Cancer-

Miracle of miracles; a business acquaintance of Mr Maxwell, one Myles Saunders who suggested I see you, for treatments— of which I did, and thankfully, so— for after treatments I visited a Cancer Clinic in Laguna Hills, a biopsy proved your treatments were successful and I so appreciate and thank you.

Sincerely,
C. Gladys Maxwell.

WEBSTER J. MCCORMACK
171 Woodland Drive
York, Pennsylvania 17403
Phone: (717) 854-6720

January 10, 1990

SUMMARY OF POLYMYALGIA RHEUMATICA AND TREATMENT AT EBM/KYTTARON PAIN CLINIC AGOURA HILLS, CALIFORNIA

This memorandum contains a summary of the symptoms and treatment of what has now been diagnosed as Polymyalgia Rheumatica (PMR) and the results of all sorts of treatment to date.

The story really begins in the early 1980's when a numbness occurred in the lower lip area after injection of novocaine by my dentist. I went to see Dr. Malcolm Weiss, a Neurologist. Dr. Weiss gave me a thorough neurological examination and discovered that I was extremely weak in the arms and legs. He questioned me considerably concerning this and all I could relate was that "Yes, I was not as strong as I use to be - I could not hit the golf balls as far as I use to and I noticed I could not throw the fertilizer bags around as readily as before." I had some soreness in the arms and legs but not what I considered pain. Dr. Weiss could not understand this and sent me to the University of Maryland Hospital in Baltimore for a confirming examination. They brushed off the weakness and recommended Vitamin B Complex for the numbness in my lip.

During the next year or so pain began to develop in my upper arms and upper legs and in my neck. I reviewed this with Dr. Hoover, my family Physician, and there was no specific diagnosis or treatment. In the winter of about 1985 which I spent in Naples, Florida, the pain got more severe. The doctors at our Substance Abuse Center recommended that I see a Chiropractor, Dr. John MacDonald. I did this and he gave me a Chiropractor treatment followed by special massages of my muscles on machines which he possessed. He strongly recommended that I religiously continue swimming (which had become burdensome). This treatment continued for the next several years. I received relief from Dr. MacDonald's treatment, but no cure.

The pain progressed and the stiffness in my neck got so severe that I could barely turn my neck in any direction. It was just about stuck dead center. The pain in the muscles of my upper arms and upper legs was quite severe. When I came home from Florida I went to Dr. Hoover and told him that I could not stand the muscle pain any longer and I could barely sleep at night with the stiffness in my neck. I wanted him to send me to some hospital where they might be able to help me. At this point, Dr. Hoover suspected PMR and sent me to the hospital for a blood test and prescribed Prednisone in a heavy dose. Within 24 hours all pain left my body, my neck turned in all directions and I went up on the roof and cleaned out the gutters.

I continued the Prednisone for the next year and a half with good success but no final cure. I had occasional flare ups and could not get completely off the medicine. There were a lot of other side effects on my body. A summary of all medications that I took since that point and the results are given in the report of Dr. Ben Hoover, dated October 30, 1989.

In September of 1989, I attended a conference in Anaheim, California and met a Mr. Evans Rapsomanikis. We were both attending a conference prepared by Dr. James McKeever and Dr. McKeever introduced me to Evans. Evans was an Engineer-Physicist and had developed many of the electronic control systems of aircraft and secret defense programs for the military. He had an early medical background and believed that many diseases of the body were caused by deficient cell structure in the molecular makeup of the body. In particular, he believed that there was a deficiency of electrons in cells which caused many diseases. He went to work and developed a machine which provided free electrons to the body so that the body could develop new cells that were perfect to replace deficient cells and cure certain diseases. He has been doing this for some 25 years and has conducted much research with his own money. Literature on the work of Evans relating to Aids is enclosed herewith.

I went to California in November, 1989 for three weeks and received treatment by Evans at his Kyttaron Pain Clinic. I asked Dr. Mariano Cooper, a close personal friend in Naples, Florida and a retired Orthopedic Surgeon, to accompany me to California and observe my treatment. Mariano did this, stayed with me for a week and gave me a thorough examination which is reported in his note dated November 18, 1989. Prior to going out there, Dr. Hoover gave me a very thorough examination including complete blood work, x-rays and an MRI to determine the cause of the pain in my lower left leg which was caused by a pinched nerve in my lower back. All of this material is enclosed.

Evans and his Physician, Dr. Fred Hering, with the agreement of Dr. Cooper, took me off all medication the very first day

---

I appeared at the Clinic. I began treatment at this time. Needless to say, during the next 2 or 3 days pain returned to the muscles in my upper arms and upper legs and my neck. By the end of the first week of treatment, I could say that there was a slight decrease in the pain level which had returned. Also, with the return of pain without medication, I became considerably weaker - that is, I no longer had strength in my arms and legs (I could bearly lift a book with my right arm).

At the end of the second week of treatment, improvement was very noticeable. I would say that the pain level had reduced by a third but my lack of strength was still unimproved. During the third week of treatment, my body was able to take the full input of his machine during the latter portion of each treatment. By the end of the third week when treatment was finished, the pain level was about 40% of what it had been after several days of the cessation of medication. Strength was returning to my arms but not in the same ratio as pain reduction. Evans and Dr. Hering advised me that I would continue to improve for about another month as a result of their treatment. They recommended that I return for one week's treatment in about 3 months. They recommended that I take Vitamins C with Carbonate and E along with increasing exercise of my arms, legs and swimming.

It has been a little over a month since I left treatment at this writing. I purchased two five-pound dumbbells and have begun arm and leg exercise and swim one-half mile three times a week. I am able to do twice the exercise today compared to when I started one month ago.

The pain has nearly left my body. When my muscles tense due to the cold weather up north, I have some pain but nowhere near what it was before. I take no medication other than the vitamins. There is a very definite increase in my strength level and I look forward to trying my golf clubs in Florida next week. I intend to return to California for treatment in the Spring.

Webster J. McCormack

Webster J. McCormack

WJM:pm

c.c. Dr. Benjamin Hoover
Dr. Mariano Cooper
Dr. Ray Wilson
EBM/Kyttaron Pain Clinic
Travelers Insurance Company

WILMAC CORPORATION

July 23, 1990

Evans A. Rapsomanikis
5809 Kanan Road, Suite 605
Agoura Hills, CA 91301

Dear Evans:

I hope this letter finds you healthy and business prospering. The enclosed article on Cell Research in a recent issue of the Wall Street Journal reminded me of you and your work.

All is well with me - in fact, all traces of the PMR in my body are completely gone. I do have a bit of arthritis in my neck and want to get out to spend a week of treatment with you but business has been booming and my work hours have been long and enjoyable - just like you. Hopefully I can break loose some time in the next couple months to get out and spend a week with you. I believe treatment would help my arthritis in the neck.

I have been very busy trying to get a new retirement community off to a fast start and have been unable to even think about the use of your treatment in our hospital in Florida. Business has been very good down there, in fact, we are having our best year ever. I have talked about your treatment with our Medical Director and given him all of the literature you gave me. He is interested and we intend to bring him to Agoura Hills for a look-see when I come out for treatment. I believe I had mentioned this to you - the problem is for me to make time to get out there. Hopefully we can do it sometime this fall.

Please say hello to all of the fine people I met when I was there last November. We think of you frequently.

Sincerely,

Web McCormack

Webster J. McCormack

WJM:hb
Enclosure

209 NORTH BEAVER STREET, P.O. BOX 5047, YORK, PENNSYLVANIA 17405 PHONE (717) 854-7857 FAX (717) 846-2594

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Robert F. Cathcart III, M.D.
127 Second St., Suite 4
Los Altos, CA 94022

June 26, 1987

Dear Dr. Cathcart,

Following up my telephone call, I am enclosing the two articles I described, by Mr. Evans Rapsomanikis, on his bio-physical breakthrough in the treatment of infectuous diseases.

As I said, there is far more to Mr. Rapsomanikis's discoveries than becomes immediately apparent from the articles. To put it bluntly: there is a rapid and effective systemic cure for infectuous diseases, and Evans Rapsomanikis has it!

In his Camarillo factory Mr. Rapsomanikis builds low-voltage devices which flood one's body with free electrons, directly restoring intercellular energy levels and rebalancing tissue polarities, all while sitting comfortably in a lounge chair.

You can physically feel your healthy energy levels returning, as simultaneously billions of infectuous agents are being harmlessly electronically neutralized. My nasty Rheumatoid Arthritis/Allergies/possible EBV were knocked out in two 2-hour sessions while I was reading a book! All this without unpleasant side-effects, Herxheimer, or toxic reactions - just peace, power, harmony steaming into my body, restoring me. The feeling is like an ascorbate high, raised to an exponential power - it's uncanny.

This treatment, Dr. Cathcart, is beyond ortho-molecular medicine, it's ortho-nuclear or, as Mr. Rapsomanikis calls it "bio-morphic" restoration through electronic stimulation/acceleration of the body's natural healing potentials and cleansing processes. He has opened the door to a new age of benign, non-toxic, non-invasive medicine and I nominate him for the Nobel Prize in servitia hominum. The end of pain, infection, suffering is in plain sight! His devices can cure AIDS (8 out of 8 patients to date are back at work - symptom-free). He can induce closing of deep surgical wounds in a day, knit a fractured bone in a week! His electron-flush is the ultimate sterilizer: no danger of infections in combat or field surgery; accelerated wound closing and healing without antiseptics/antibiotics. What a glorious, exciting, blessed step forward for medicine, for mankind, for all life!

Dr. Cathcart, you know me as a sober, responsible businessman. I hold 14 patents in technology and optics and am not given to irrationality. I have come to know you as a caring physician, inventor and scholar. Over the last 2 years, you have taught me to listen to my body, helped me cope with my condition and improve. I owe you, as well as Dr. Bingham, who helped me in my fight against Arthritis, a great deal of gratitude.

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-2 -

I am whole again, feel so well! I want you and Dr. Bingham, and the Arthritis Foundation, and the world to know there is hope right here and right now for for anyone suffering. Mr. Rapsomanikis will lease his devices to select physicians who care to help their suffering patients right now. Catch a flight down here and have a look. The burdens of suffering and affliction on this planet have increased far beyond our institutional capabilities to cope. A general remedy or panacea is highly indicated. The free electron will be the answer. I consider it vital that Mr. Rapsomanikis' devices are placed in local clinics now, and in universal use tomorrow. In the interest of science, ethics and humanity I plead with you, Dr. Cathcart, to get acquainted with Evans Rapsomanikis and his bio-morphic answer to pain and suffering. You will thank providence for this extraordinary opportunity.

My best regards and wishes to you, as well as Crystal "Nightingale" and Margaret.

Cordially,
VISIONS
Gerard
Gerard M. Du Corday
Vice President

GMDC:mab
Encls: (2)
cc: Dr. Robert Bingham

54-718 216

[illegible] V

MAKERS OF WORLDWIDE PATENTED "CRYSTAL® SHIELD" PRODUCTS

October 13, 1990

Paradise Pain Clinic
Mr. Evans A. Rapsomanikis
3900 Paradise Road, Suite "F"
Las Vegas, NV 89109

Dear Evans:

Just a few lines to say hello, I miss you and to update you on my health. May 25, 1990 I came to you for treatment. I had a lung disease called histecytosis X. The diagnosis was progressive veriables, degeneration and eventual death. I had no hope as the only treatment was steroids or chemotherapy which is worse than the disease itself. I was extremely tired all the time, I could't work or do much of anything. I was sick constantly.

A wonderful man in whom I have never met named "Gary North", sent me to you for treatment. He funded my trip. He obviously had a lot of faith in your machines and treatment. I will forever be grateful to this man.

Evans, you treated me for three weeks. I have never had such professional treatment in my life. Everyone was so kind and concerned about my health. I will recommend your clinic to everyone.

I feel wonderful. I have so much energy now. I don't get sick all the time, and I now have a job. God worked through the Paradise Pain Clinic to heal me! I send my thanks and love to you and your entire staff. I am a new person now thanks to Paradise Pain Clinic!!!! God bless you all.

Sincerely,

Donna Sheikh

Donna Sheikh

p.s.

If you ever talk to Gary North, please give him my love and gratitude. To this day I have never met him, don't even have his address to write him a letter and give him my personal thanks and gratitude. Please tell him that I always pray for him and ask God to bless him for giving to me. Thank you Evans!

Tell Christina, George, and your two wonderful technicians I send my love and hope they are doing well. My love and prayers are always with you.

December 3, 1990

Dr. Evans A. Rapsomanikis
Paradise Pain Clinic
3900 Paradise Road, Suite F
Las Vegas NV 89109

Dear Dr. Evans:

Since I first went on the Bio-Ionic System three weeks ago, I am a new person with a brand new life.

I was diagnosed as having Chronic Fatigue Syndrome recently, with the possibility of having it most of my life. After the first BIS treatment on that comfortable chair, I felt my brain begin to clear up and energy came into my body which I had never before experienced in all of my 57 years. The chronic back pain has completely gone as well as the migraine-type pain in my head and the partial paralysis in my right leg, confusion and inability to speak clearly is also gone. I am currently easing off all chemical drugs in my body and I feel wonderful.

Let me tell you some of my medical background so you can fully understand why I am so excited about this treatment I have just finished.

I was born with malnutrition and rickets and had several seizures before I was one year old which caused me to spend the first five years of my life in a children's hospital. During my childhood I experienced all the normal childhood diseases - more than once. Four to six times each year I would experience the flu which would put me in bed with high fevers for two to three weeks. During adolescence, the menstrual cycle became worse and worse until I finally had to have corrective surgery at 21 years with a complete hysterectomy at age 35 years. The black-outs that occurred during these years got worse and worse. All the physicians told me this was all in my head and would send me to psychiatrists. In my lifetime, I have been under the care of over eight psychiatrists, all of which have told me that there is nothing mentally wrong with me, but that it has to be a physical problem. No doctor would acknowledge that there could be any physical problem.

Finally, in 1973, I had the first of many so called "mental breakdowns" which kept my body so fatigued I didn't want to move or make any decisions or talk to anyone. The last of these breakdowns occurred in 1983 where I was hospitalized for 6 weeks in a mental hospital. After complete tests by 3 psychiatrists, I was told that there was nothing wrong with me mentally, but that there had to be a serious physical problem. Since this date, I have had to be on chemicals to keep the brain functioning properly; however, I have not had the ability to concentrate for any period of time because of the severe headaches, lower back pain and the inability to use my right leg which causes the rest of my body to be in pain also. All desire to live left me; I felt I was wasting away my life which, at one time, caused me to become suicidal.

During the past year my symptoms had become worse than ever before; however, the day I went into the Paradise Pain Clinic for my first treatment, I was feeling the best I had in over nine months. When I left that day, I couldn't believe how good I felt. Looking back, I realized that my best day was very bad in comparison.

Every day I feel better and better. My family and friends are totally amazed at the change in me. My voice sounds like it has 'life' according to one friend. My mother said that she has never seen me so well.

I thank God for giving this technology to Dr. Evans, and I give God all the glory for opening the door for me to be rid of this body full of pain and chronic fatigue.

Thank you Dr. Evans, and all your wonderful staff, for all your support and encouragement, and for caring. May God bless you in getting this simple approach to wellness out to the common people who are suffering needlessly because of the lack of medical knowledge.

Sincerely,

Gayleen

Gayleen Deininger

I forgot to mention two things:

1. my allergies had gotten worse before the treatments and now I am able to eat all foods.
2. I am now free from nightmares and sleep throughout the night.

Alice M. Bello

May 25, 1990

TO WHOM IT MAY CONCERN:

My reason for seeking help at the Paradise Pain Clinic involved several health issues. After twelve years on Cortisteriods, I suffered from the lack of adrenal function, deteriorated skin tissue, damage to bones which included breaking bones in both left and right feet, pain in my hands and fee, neck pain and severe bruising and general muscle weakness.

After the first treatment, I noticed a dramatic increase in energy. Having been diagnosed with Chronic Fatigue Syndrome, the increased energy was a miracle. When treatment began, the staff at the Pain Clinic were a bit frightened when removing the electrodes from my hands and feet. It was a slow process that none of us enjoyed! At the time of the last treatment, the skin tissue on my hands and feet had become stronger and not as much care was necessary.

In addition to attention to the adrenal gland function, electrodes were placed at the lung points. The most dramatic episode during my withdrawal from cortisone occured when the staff had to carry me into the Pain Clinic. My lungs were so congested that I was unable to breath, let alone walk. I think I frightened the staff to death. My breathing was so labored that during the treatment a lap tray had to be placed on my lap so that I could lean forward during the treatment. It was impossible for me to rest back in the chair. By the next morning, I WALKED into the Clinic for treatment. We were all amazed. I know that it was the treatment process that helped resolve the severe congestion and lack of energy.

It is now seven months since my last treatment. When I left the Clinic, I no longer experienced pain in my feet, neck, hands or knees. My skin was beginning to repair itself and has continued to do so. We are continuing the slow process of withdrawal off cortisone. It is obvious to me that I am beginning to experience adrenal function where there was once none. There is no evidence of Chronic Fatigue Syndrom or Herpes Simplex (cold sores) in my system. I am grateful for all that the PARADISE PAIN CLINIC has accomplished and continues to accomplish. Their work has given me a new life!

Sincerely,

Alice M Bello

ALICE M. BELLO

Patient: George E. Smith
Doctor: Milton Denmar, M.D.

To Whom It May Concern:

Six months after treatment for Epstein-Barr Virus, I am in good health again. My weight is back to normal, and also my energy and mental acuity.

Symptoms that brought me to the doctor's office were: rapid weight loss, fatigue, weakness, aches & pains in joints, arrythmia with pulse changing rapidly and skipping beats; inability to concentrate, some memory loss, depression and loose bowels. My temperature never exceeded 96.9 & was often lower.

I was tested in Feb., 1987, for E.B. Virus, & food allergies. I was found to have many food allergies and also malabsorption, as well as the E.B. Virus. I was put on a very restrictive diet, excluding all foods I was allergic to. I was given Prozac 20 mg, Isoptin SR, 240 mg, plus vitamins, minerals, amino acids, germanium and Barley Green.

Later I wore a 24-hr. heart monitor, the results showing that my heart was in fibrillation many times (at least 4 serious) in the 24 hr. period.

In 1989 I was given Adenosine Phosphate injections for about 12 months. My health was improved enough so that I could work part time. Then it seemed I reached a plateau, with no further improvement.

In April, 1990, I went, on my doctor's advice, to the Paradise Pain Clinic in Las Vegas, Nevada, where I received Bio-Ionic treatments, 3 hours per day, for 10 days. At the end of that time I began to notice great improvement both physically and mentally, and improvement continues.

Very Truly Yours,

G.E. Smith

G.E. Smith

Cleveland Heights, OH
October 20, 1990

TO WHOM IT MAY CONCERN:

In 1984 I was diagnosed by three different physicians as having the Chronic Fatigue and Immune Deficiency Syndrome. During the decade before that I dealt with ever more frequent episodes of "flue-like" symptoms: increased head pain, fever, exacerbated sore throat, sore joints, depression, inability to concentrate etc. By 1981, these episodes occured once a month; by 1986, the symptoms were more or less chronic, and accompanied by fatigue.

The changes I have experienced in my condition since the first treatments in April of this year are just sort of miraculous. While I had experienced a slight improvement in the CFIDS and some lessening of symptoms by February, 1990 (due to the care of Fuller Royal, M.D., gegun in July 1989), I was not prepared for the amost "instant care" that occured in May. I'd been unable to work more than one day per week through the month of April' by mid May, I felt so energized that I took on a 25 hour per week job in upstate New York, which turned out to be a 50 hour job. To my amazement, I became severely ill once Once, at the very beginning, and felt quite well throughout the summer. So well, in fact, that I am now working a full-time chaplaincy job here in Cleveland.

I would never have dreamed in October, 1989 that I would be doing so well a year later. My health is not "perfect" -- I still get headaches, though not too often, and I need more sleep than most people. Yet I have much more energy than I've had in a long time.

I am very grateful to Evans Rapsomanikis and for the work he has been doing. The Bio-Ionic System Device has certainly helped me. I hope that many others may benefit from it in the future.

Sincerely,

Brigitte E Brunhart

Brigitte E. Brunhart

JAMES H PLOCH
515 BROAD ST
CLIFTON, N.J. 07013
201-546-2470

4-2-91

Dear Evans-

This is brief thank you for the help and kindness I received at the Paradise Pain Clinic during my visit in January 1991. My condition, which I can best describe as chronic fatigue, has improved tremendously. I began to notice subtle, yet immediate benefits from the very first session on your Bio Ionic System. As the treatments increased to the full twelve I felt revitalized, and energized to a degree not experienced since childhood. Besides feeling physically better my emotional attitude also improved dramatically. To my surprise, the most fundamental thought processes, which I had believed to be fine, suddenly had a fog removed, and I was again confronted with a clarity of mind that I had slowly been deprived of without even realizing it. Another startling benefit from the treatments I received was the cessation of chronic pain in my right knee. This inflammation was a condition that I had become accustomed to, originating during my athletic years from age 14 to 22, and continuing through my present age of 28. The whole experience was quite remarkable, and will not be forgotten any time soon. In fact I hope to make at least one or two yearly visits solely for the cleansing effect the treatments had on my system. For me the treatments had an overall beneficial tonic effect, besides helping specific problems. I would also mention that before I would consent to any invasive treatments involving surgery or toxic chemicals prescribed by dogmatic physicians, I would first undergo treatments on the Bio Ionic System. If I were so unfortunate to require invasive western medical techniques, I would without hesitation plan on convalescing at one of your pain clinics. Receiving treatment at the Paradise Pain Clinic was the only positive health care experience I can remember having.

Evans, the more thought given to the benefits I received, and the possibilities the Bio Ionic System offers to mankind, the more thankful I am for God's gift of creative genius, and the untiring dedication that was granted to you. With all my heart, I wish you good health and happiness.

Yours Truly,
James H. Ploch

Skip Sargent
1045 "A" Davis Ave.
Glendale, CA 91202
3/18/88

Evans Rapsomanikis
Monrovia Center For Health Care
212-A West Foothill Blvd.
Monrovia, CA 91016

(818) 357-2226

Dear Evans,

This is a note to let you know the final outcome of my treatments on the T.E.N.S. device.

It's been a year since I first came to you with an injured right knee.

I'd twisted it, and the next day was unable to bend it more than about five degrees. It was somewhat swollen, and felt like something absolutely awful was going to happen if I forced it to bend further, as if it'd just "come apart."

My orthopedic surgeon felt it was probably a torn cartilage, and "at best," torn ligaments.

Neither of these injuries heal without surgury, and he wanted to do an arthroscopy to locate the damage and (mostly) repair it. I was reluctant, and wore a brace in the meantime.

It was a month later that I finally came to see you: I only wish I had sooner, as I understand that IMMEDIATE treatment can give truly dramatic results.

As it was, I received 16 treatments over a period of seven weeks. Each time I noticed another increase in motion the next day. (I had specific measurements: how much closer I could come to bending my knee enough to ride my motorcycle!)

Today, I'm able to fully participate again in my martial arts training, running, weight lifting without any restrictions or undue caution. My doctor just shrugs... "one of those things."

But I certainly know where to go if I ever have a similar injury.

I thank you for your help, and I hope your device receives complete and worldwide recognition for what it can do to help humanity.

Sincerely, Skip Sargent

Evans Rapsomanikis treated my left hand, large knuckles of the index and middle fingers. Before treatment these specific joints were swollen about three times their size and very sore.

After the full series of treatments, the swelling and pain was greatly reduced, and the flexibility increased. It has been over three months now, and those specific areas are still almost without pain, the swelling has remained as it was after treatment, and the joints are still flexible.

When I have other flairups in my arthritis throughout the other joints in my body, those treated by Mr. Rapsomanikis still seem to remain healthy and do not flair up.

Anne B. Mangum
May 31, 1984

Mr & Mrs Arthur Kay,
"Berith",
Brown Barn Farm,
Bradshaw,
Bolton, BL2 4JP.

Telephone: (0204) 852773

3rd. March, 1991.

Dear Evans,

I am sorry to be so late in letting you have an up-date on Justin, we have been inundated with television cameras these past few weeks, however the programme has now been broadcast and things are returning back to normal.

Justin is very much better. The headaches have disappeared together with the chest pain, night sweats, and most of the pain in his limbs, though he still has some pain at the end of the day which is probably attributable to the extra walking he is doing around the house and are just the normal aches which would be expected from limbs not used to much exercise. He is now walking without the aid of the furniture at home and has graduated to walking sticks when outside. The nausea is much less troublesome and his energy level has increased also. He does still experience some fatigue, however, he recovers from his exertions more quickly now than in the past.

He is like a different child. He laughs a great deal, is taking an interest in everything, is able to do more school work and actually be capable of learning new things which was impossible before he came to you for treatment. He has not yet returned to school though he is hoping to start again in the summer term. He becomes more like his "old self" everyday, we are beginning once more to see the Justin we despaired of ever seeing again. He sends you his love and thanks, I know he thinks of you often.

We just don't have the words to adequately thank you for all that you have done for our young son, we believe your treatment to be really wonderful and would love it to be available in this country. I have spoken to Justin's Paediatrician about it and he is very interested. He did say that he would like to come and see you at some future date, I do hope that he does.

As I mentioned earlier the T.V. programme has been broadcast and it has aroused such interest that the B.B.C. are repeating it in June. It received the largest viewing figures of any regional documentary anywhere outside the London area. I do hope that you have received a copy, I asked them to send you one, please let me know if you haven't received it and I'll do my best to get one to you.

Arthur sends his love to you and your staff, and thanks you once again for all the care and kindness you showed to both he and Justin during their stay with you. He is sorry he has not had time to write to you. He and Justin have told me so much about you that I feel I know you all too. May God bless you.

Yours,

Betty Leech
22300 S. W. 162 Ave.
Miami, FL 33170 (bus.)
FAX: (305) 271-7688

May 23, 1991

Evans A. Rapsomanikis
Paradise Pain Clinic
3900 Paradise Road
Las Vegas, NV 89101

Dear Evans:

Just a note to let you know how I am doing 90 days after treatment at your Bio-Physical Therapy Treatment Center in Ontario. Having had multiple sclerosis for about 18 years with a fairly set pattern of problems which never prevented me from doing what I wanted to do, the past year was something of a rude awakening. My right foot had been weaker for ten years but "foot drop" was a new problem and I began using a cane in June 1990. Fatigue was the larger issue and I was just too tired to even take reasonably good care of myself--not to mention my husband and four-year old daughter (born when I was thirty-seven years old!). Maybe the demands of a child plus turning forty led to a worsening of my condition.

Throughout the past 18 or so years I have taken Prednisone periodically in high doses when my symptoms worsened. In December of 1989 loss of functional vision for ten weeks prompted me to begin to look for other treatments. Interferon has gotten lots of attention as a promising new drug so I was very excited to be accepted into a research project being conducted at the M.S. Center of the University of Miami. Nine months later (January 1991) I was certainly no better and getting desperate. I would recommend that anyone try Interferon but it did not work for me. Intravenous ACTH (which I had in 1972) and chemotherapy were alternatives offered.

Knowing that I was becoming disillusioned with traditional medicine, a friend loaned me a book on Laetrile by Ed Griffin and other similar materials. Curious about that vitamin, I called Mr. Griffin and he suggested I contact you. As you know, I contacted everyone I was able to track down in the references you sent with the other information about the BIS device. Everything was positive.

May 23, 1991
page 2

As I said earlier, my pattern of M.S. symptoms is very familiar to me so changes are easy for me to spot. From the first couple of treatments I noticed a change in bladder function. The Doctor in Ontario (who was wonderful) said that my system was being cleaned out, toxins removed, etc. During the three weeks of treatment I had good days and not as good days but overall felt stronger all the time. Balance and coordination improved also. I did my own grocery shopping which I had not done in six months prior to this.

Unfortunately I did not follow your instructions to take it easy for a month or so when I returned to Miami! Having energy for the first time in years, I have worked harder and been more active, rested less and made more demands on my body than I should. Still, the numbness is gone from my left hand, my right hand is stronger, the foot drop is no worse and seems to be improving slowly and I have enough energy to do all I really want to do.

M.S. is a very screwy illness since it affects every person differently and has such a wide range of symptoms. Your theory of allowing the body to draw energy to repair itself makes sense to me since cellular repair and development of alternative nerve pathways are what is needed when the myelin sheath is destroyed as in M.S. The BIS treatments seemed to be just what my body needed to "jump start" my system and give me the energy to be able to pay more attention to my nutritional status and thereby continue the repair process.

If there were a clinic on the East coast I might be able to afford to have additional treatments sooner! I do believe that the treatment would be effective for just about any ailment because of the boost it seems to give to the system. Please keep me informed of any new clinics that open.

Thank you again for the treatments and for the caring staff of the clinic. I look forward to seeing all of you again in the near future.

Sincerely,

Betty Leech

Colin Fretwell
30 Lichfield Road
Moss Shaw, Radcliffe
Manchester, M26 OLZ U.K.
13 May 1991

Dear Evans:

A first letter, on behalf of Julie and myself, now that we have been at home for three weeks.

The journey from Las Vegas was fairly low key and almost uneventful. The flight to New York was delayed by twenty minutes due to overbooking. They actually requested that we give up our seats when we arrived at the gate and had I been on my own, would have been very seriously tempted to. But eventually, after the increasing phases of financial bids, four passengers gave up their seats for 550 dollars each! From New York there was a four hour delay, due to a technical fault on the aircraft, so we eventually arrived at Manchester airport at 4:35 a.m. on Saturday. Julie's Mum's face was a joy to behold! It hadn't registered with me, of course, being with Julie for the six weeks and seeing a gradual improvement, that there would be such a noticeable difference to someone who had a month and a half gap. Julie continues to improve, slowly but surely, with the occasional combination of headache and listless feeling, but we constantly reinforce and encourage her and ensure that she is keeping to your exercise, diet and vitamin regimen. Julie wouldn't wish me to continue this without sending her love, her deep respect and boundless gratitude to you.

The most pleasant experience, from the benefits of your treatment, was last week when we accompanied Julie to our local health centre to check in with one of our panel of three doctors. (This has to be done periodically for Julie to qualify for welfare/benefit payments.) This doctor, who was virtually completely skeptical two months ago, after seeing Julie is not at all disbelieving now, so we have plied her with more brochures and verbal information and she actually admitted that a United Kingdom hospital/pain clinic would be a very good idea!

We have been in touch with the Kays. I'm pretty sure that Justin is starting full-time school this month. I won't say more as I know they correspond with you, but we'll be attending a support group meeting tonight so we'll see them and I'm ready and willing to be bombarded with queries and questions reference our six-week visit. Meanwhile we look forward to reading and/or hearing about your intended Trans-Atlantic press release.

My greatest difficulty, Evans, is how to conclude this letter, being no great creative writer. It would be impossible to say anything original about you, as you will have already received the far-reaching accolades that you merit so completely. Thank you for being the greatest, kindest humanist we have ever known.

page 2

Thank you for so readily and selflessly relegating your personal life for the benefit of mankind. Thank you for all your precious and unbelievable time that you gave to our family. The greatest thought, Evans, is that if only part of your boundless goodness affects all who come into contact with you, the human world would have become a far more useful, tolerable, and bearable world. We hope that your radio, TV and video output will cause the Campaign of campaigns to spread more rapidly.

Before this, my first visit, I already had the greatest possible respect and feelings for the USA. Due to the wonderful, unforgettable staff of the Paradise Pain Clinic, this respect and these feelings have been totally vindicated. Their combined effect on myself resulted in a firm resolution not to make this my only visit to the States. Through yourself they number the finest people I have ever met - Love to them all and fondest remembrances of: Dinah, Stan, Glenis, Sharon, Christine, Bea, Zoe, and Natalie.

May all your wishes and hopes for yourselves and your families be fulfilled.

With the greatest affection.

Colin

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 31 1992

The Honorable Ron Wyden
Chairman, Subcommittee on Regulation,
  Business Opportunities, and Energy
Committee on Small Business
House of Representatives
Washington, D.C. 20515

Dear Chairman:

This is in response to your April 10, 1992, letter requesting answers to questions raised during the April 9 hearing regarding trends in medical fraud and quackery. We regret the delay in our response.

The enclosed report provides answers to the questions that correspond to those in your April 10 letter. If we may be of further assistance, please let us know.

Sincerely yours,

Marc J. Scheineson
Associate Commissioner
  for Legislative Affairs

Enclosure

cc: The Honorable Jan Meyers
    Ranking Minority Member

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Subcommittee on Regulation,
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STAFF MEMBER
202-225-2886

April 10, 1992

Dr. David Kessler, M.D.
Commissioner
The Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler:

I appreciate the cooperation of the Food and Drug Administration in assisting the Small Business Subcommittee on Regulation, Business Opportunities and Energy and the Aging Subcommittee on Health and Long-term Care in their joint investigation into recent trends in medical quackery. I specifically appreciate the testimony of Dr. Ronald Johnson, the FDA's Director of the Office of Compliance and Surveillance at the Center for Devices and Radiological Health at the subcommittees joint hearing on this topic on April 9, 1992.

Subcommittee members raised several questions at the joint hearing that require additional information from the FDA. Please provide the subcommittees with answers to the following questions for the hearing record:

1. What priority does FDA give to medical fraud and quackery investigations?

    A. At FDA, who determines whether the Office of Compliance and Surveillance has sufficient resources to conduct investigations into quack device practitioners and manufacturers.

    B. Have any internal requests been made to expand the manpower and other resources available to the Center of Compliance and Surveillance? What is the status of that request?

2. Would it be useful for FDA to have investigative subpoena powers, similar to those granted to the Drug Enforcement Agency, when pursuing violations of the FDA labeling and device regulations?

3. Please provide the subcommittees with information regarding any FDA investigation of healthcare "CARTELS": How many? What type? And, has the FDA had any success in this area?

4. Please provide the subcommittees with information regarding FDA efforts to coordinate fraud investigations with insurance companies.

   A. Are insurance companies cooperating with FDA fraud and quackery investigations?

   B. What statutory limitations prevent better cooperation between government enforcement agencies and insurance companies?

5. What does the FDA believe can be done to bring state-licensing authorities more actively into the battle against medical fraud and quackery?

6. More and more, medical and financial records are being stored electronically on computers thus eliminating a traditional paper-trail that has been useful in previous fraud and quackery investigations. What steps is the FDA currently taking to meet the challenge of electronic record keeping in its investigations?

7. Finally, according to written testimony that FDA submitted for Mr. Johnson, the FDA has established a toll-free telephone line to "further combat medical fraud." The line's purpose, said Mr. Johnson, is to "allow callers to ask medical staff [at FDA] about questionable promotional activities and practices or alert us [FDA] to healthcare products that may require FDA regulatory attention."

   In an effort to verify the utility of this program, Regulation subcommittee staff -- without identifying themselves -- called the FDA's toll-free medical quackery hotline (1-800-238-7332) on April 8, 1992, to inquire about a medical promotion the Subcommittee on Regulation had received in the mail. Staff asked the FDA about the marketing and use of a medical device called a "cosmetic laser." This device is currently being marketed by The International Society of Cosmetic Laser Surgeons, Inc., located in Hermosa Beach, California. (See attached letter for a description of the product in question.)

Dr. David Kessler
Page Three

FDA hotline staff was confused both about how to process the request for information and how to proceed. Regulation Subcommittee staff was passed on to 4 different FDA officials -- none of whom could provide any helpful information. Finally, staff was put in contact with a Mr. Purvis. Mr. Purvis told my staff he was vaguely familiar with the device mentioned, but that the FDA has "nothing to do at all with the practice of medicine," and probably would not be the best place to find out specific information about this company or its device. He suggested calling local medical societies for more information on the use of the cosmetic laser.

As a result of this inquiry, questions now exist as to the utility of the Hotline. Please provide the subcommittees with additional information about the Hotline's mission, its operating procedures, and any steps that the Agency plans to take to streamline the process and thereby give Hotline users a greater sense that their questions are being answered and their concerns addressed.

As always, the subcommittee appreciates your cooperation and assistance. Should you have any questions regarding this request, please don't hesitate to contact Graydon Forrer of the subcommittee staff at (202)225-7797.

Sincerely,

Ron Wyden

RON WYDEN
Chairman

RW/gjf
enclosure

INTERNATIONAL SOCIETY OF COSMETIC LASER SURGEONS, INC.

415 Pier Avenue • Hermosa Beach, CA, USA 90254
(310) 372-8802 • FAX: (310) 318-6369

MEMBERSHIP REQUIREMENTS

Applicants must be Board Certified in one of the following specialties:

☐ Otolarygology
☐ Dermatology
☐ Cosmetic Surgery
☐ Oral/Maxillofacial Surgery
☐ Scientist, Physicist, Engineer
☐ Plastic/Reconstructive Surgery
☐ Ophthalmology
☐ Gynecology
☐ General Surgery
☐ Nurse, Assistant, Technician

MEMBERSHIP APPLICATION CHECKLIST

The following documentation must be submitted with your application:

☐ Current Application
☐ Current Curriculum Vitae
☐ Current Photograph
☐ Membership Fees
☐ Copy of current unrestricted medical license

MEMBERSHIP FEES

- ■ $250.00 plus $50.00 non-refundable processing fee.
  (Total of $300.00.)

- ■ Nurses, Assistants, Technicians:
  $50.00 plus $50.00 non-refundable processing fee.
  (Total of $100.00.)

If all of the above documentation is not submitted, the application cannot be processed and will be returned.

Please make check payable and submit to:
INTERNATIONAL SOCIETY OF COSMETIC LASER SURGEONS, INC.
415 Pier Avenue • Hermosa Beach, CA, USA 90254
(310) 372-8802 • FAX: (310) 318-6369

The International Society of Cosmetic Laser Surgeons, Inc.

415 Pier Avenue • Hermosa Beach, CA, USA 90254 • (310) 372-8802 • FAX: (310) 318-6369

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March, 1992

Dear Doctor:

Exciting things are happening in cosmetic laser surgery.

New and innovative laser techniques have gained favor with physicians and patients around the world. Lasers are now available in most hospitals and outpatient surgery facilities. The public is sophisticated and aware of advances in technology and new techniques.

It is with this background that we enthusiastically announce the formation of the INTERNATIONAL SOCIETY OF COSMETIC LASER SURGEONS, INC. (ISCLS). There are exciting plans for the near future. The First World Symposium will be held June 5, 6 and 7, 1992, followed by a Live Laser Surgery Workshop June 7 and 8, in Philadelphia. This is your opportunity to learn how to get started, what equipment you will need and how to do safe and effective cosmetic laser surgery. If you are already doing some of these procedures we welcome your original paper for presentation at this meeting.

In addition, a special issue of the American Journal of Cosmetic Surgery (AJCS) will be devoted entirely to cosmetic laser surgery. Our experts are already vigorously working on this issue.

We are also planning live, small group, directly-in-the-operating-room workshops at designated facilities around the world. Membership in the ISCLS is a prerequisite. Literature will be available shortly describing these programs in detail.

Send your membership application now and make your plans early to attend the June 5, 6 and 7, 1992 World Symposium of Cosmetic Laser Surgery and Live Laser Surgery Workshop on June 7 and 8, 1992, as space is limited.

For more information call or write:

International Society of Cosmetic Laser Surgeons, Inc.
415 Pier Avenue
Hermosa Beach, CA, USA 90254
(310) 372-8802
FAX: (310) 318-6369

Sincerely,

Laurence M David
Laurence M. David, M.D.
President, ISCLS

Julius Newman, MD
Julius Newman, M.D.
Founder, ISCLS

The International Society of Cosmetic Laser Surgeons, Inc. announces the First World Symposium on Cosmetic Laser Surgery

With Live Workshop

World Symposium on Cosmetic Laser Surgery

World Symposium dates: June 5,6 & 7, 1992

Location: Philadelphia, PA, USA

Faculty to include laser surgeons from Germany, Japan, South America, Spain, Sweden and the U.S. will present an intensive course on the following cosmetic laser procedures:

- **Blepharoplasty**
- **Rhytidectomy**
- **Brow and forehead lift**
- **Breast augmentation**
- **Scalp reduction**
- **Resurfacing skin and lips**
- **Scar improvement**
- **Cutaneous lesions**
- **Blood vessel abnormalities**
- **Liposuction**
- **Tattoo removal**

Laurence David, M.D., Program Chairman
Ron Kirschner, D.O., Workshop Director
Julius Newman, M.D., Honorary Program Chairman

Live Workshop on Laser Surgery

Workshop dates: June 7 & 8, 1992
(Immediately following World Symposium)

Location: Philadelphia, PA, USA

Participation in World Symposium and membership in ISCLS is a prerequisite.

Workshop limited. Please reserve early.

Fees

Symposium Fees:

Residents/Fellows	$150.00
Nurses/Technicians (member)	200.00
Nurses/Technicians (non-member)	250.00
ISCLS members	475.00
Non-members	525.00

Workshop Fee: $1000.00

Add $100.00 for payments received after May 1st.
No refunds two weeks prior to meeting.
Limited space. Please reserve early.

For more information contact:
International Society of Cosmetic Laser Surgeons, Inc.
415 Pier Avenue, Hermosa Beach, CA, USA 90254
(310) 372-8802 • FAX: (310) 318-6369

REGISTRATION FORM - World Symposium on Cosmetic Laser Surgery and Live Workshop

☐ Member ☐ Non-member

Name ______________________________

Address ______________________________

____

City ____________ State ______ Zip ________

Phone ____________ FAX ____________

Signature ______________________________

For reservation, please enclose your check for the total amount and return with this form to the above address.

Symposium fee ____________

Workshop fee ____________

Late registration fee (After May 1st) ____________

Total enclosed ____________

THE INTERNATIONAL SOCIETY OF COSMETIC LASER SURGEONS, INC.

Presents a special program for

COSMETIC LASER SURGERY NURSES AND LASER TECHNICIANS

As part of its First World Symposium, the **International Society of Cosmetic Laser Surgeons, Inc.** will present a three-day program for laser nurses, assistants and laser technicians. This program offers tremendous educational opportunities to your staff, including:

- The opportunity to assist with live, hands-on surgery under the supervision of a skilled laser surgeon.
- Training tips on safe operating procedures
- Familiarization with laser surgery equipment.

The objective of this course is to prepare and stimulate your staff as well as to provide them with helpful training tips for safety, speed, success and patient satisfaction.

DATES: **June 6, 7 and 8, 1992**
LOCATION: **Philadelphia College of Osteopathic Medicine, Philadelphia**
FEE: **$200.00 Registration Fee + $50.00 Membership Fee**
Total = $250.00

Betty Carrel, Course Director
Laurence David, M.D., Program Chairman
Ron Kirshner, D.O., Workshop Director
Julius Newman, M.D., Honorary Program Chairman

For more information contact:
International Society of Cosmetic Laser Surgeons, Inc.
415 Pier Avenue
Hermosa Beach, CA, USA 90254
(310) 372-8802
FAX: (310) 318-6369

Membership in the Cosmetic Laser Surgery Nursing and Technician Section of the ISCLS is a prerequisite. Program is limited. Please reserve early.

REPORT ON CURRENT TRENDS IN MEDICAL FRAUD AND QUACKERY

Question 1.	What priority does FDA give to medical fraud and quackery investigations?

Answer

Medical fraud and quackery investigations are given priority based upon whether the device presents a direct and immediate hazard to the consumer. These investigations are assigned priority in the same manner as other investigations -- the Agency assesses the potential for harm, and then directs its attention first to those products presenting an immediate risk. There is a direct relationship between public health impact and the priority assigned to an investigation because it is imperative that the Agency use its limited resources efficiently and effectively.

Question 1 A.	At FDA, who determines whether the Office of Compliance and Surveillance has sufficient resources to conduct investigations into quack device practitioners and manufacturers?

Answer

The Agency has mechanisms for assigning its resources according to public health priorities, and assessing the sufficiency of those resources within its budgetary allocation. The resources available for investigations into quack device practitioners and manufacturers are determined by a coordinated effort among several offices within the Agency.

The Center's overall resource allocation is determined through the budget process by the Agency's Office of Management Operations which coordinates with the Center's Office of Management Services. Following this process, a budgetary mark is determined for the Center's several offices, including the Office of Compliance and Surveillance (OCS). Within this allocation, the Center's OCS determines its fiscal priorities as well as its priorities for investigations which require field resources. OCS coordinates the allocations of field resources with the Agency's Office of Regulatory Affairs. OCS then assigns priorities for all investigations based upon public health impact, as described previously.

Question 1 B.	Have any internal requests been made to expand the manpower and other resources available to the Office of Compliance and Surveillance? What is the status of that request?

Answer

OCS has redirected resources to establish a Device Labeling Branch which is responsible for reviewing labeling, promotion and advertising claims, and issues related to fraudulent or quack devices. Two positions are currently assigned to this branch, and there are plans for redirecting three additional positions to this unit.

As a result of redirecting these resources, OCS has expanded its efforts to combat health fraud. A number of investigations are underway and several have already resulted in regulatory action. For example, this year the Agency issued warning letters for biofeedback devices, energy frequency generators and test kits for body pH and parasites which made claims for a number of diseases. In addition, increased staffing in this area will help to foster recently established cooperative programs with the National Associations of Attorneys General and the Association for Food and Drug Officials.

Question 2. Would it be useful for FDA to have investigative subpoena powers, similar to those granted to the Drug Enforcement Agency, when pursuing violations of the FDA labeling and device regulations?

Answer

The Agency does not believe it needs additional investigative subpoena powers at this time.

The Agency relies upon its traditional remedies to combat health fraud, i.e., seizure, injunction, criminal prosecution, import detention, administrative detention and banning. In addition, the Agency was provided additional remedies by the passage of the Safe Medical Devices Act of 1990, i.e., civil penalties and mandatory recalls. The Agency possesses adequate regulatory tools to take action against manufacturers promoting or selling quack or fraudulent products.

Question 3. Please provide the subcommittees with information regarding any FDA investigation of health care "CARTELS": How many? What type? And, has the FDA had any success in this area?

Answer

The Agency is aware that one growth area in health fraud pertains to health care "cartels." FDA would consider under this banner the "pyramid" type activity that links together a number of individuals conspiring to perpetrate a health care scheme. The Agency believes that in such health fraud cases, criminal prosecution is the most powerful enforcement tool. A major nationwide FDA investigation, with grand jury authority, of one of these schemes is currently underway. It is premature to judge the outcome of the effort at this time, but we do anticipate this work will be productive.

Question 4.	Please provide the subcommittees with information regarding FDA efforts to coordinate fraud investigations with insurance companies.

Answer

Establishing linkages to obtain information from insurance companies is a recent initiative within the Agency, and therefore we have no retrospective information to supply.

Question 4A.	Are insurance companies cooperating with FDA fraud and quackery investigations?

Answer

In establishing our Health Fraud Coordination Unit in headquarters, it became clear to us that the Agency will need to expand its outreach efforts beyond the traditional academic consumer and governmental channels as noted in our Health Fraud Strategy Document (copy attached).

Insurance companies will be an important link. We are at the stage where information is being compiled by and for insurance companies to help reduce inappropriate payments for fraudulent or unapproved treatments, drugs, and devices. Access to that information is part of our strategy for extramural coordination. We also intend to provide information to outside organizations within the usual limitations of confidentiality restrictions. This outreach effort will begin when the permanent staff join our Health Fraud Unit in Office of Regulatory Affairs (ORA) this summer.

Question 4B.	What statutory limitations prevent better cooperation between government enforcement agencies and insurance companies?

Answer

The statutory limitations to better cooperation between the Agency and insurance companies include trade secrets and commercial confidential information protection in the Federal Food, Drug, and Cosmetic Act, Privacy Act and Freedom of Information Act. The Agency also has a number of related regulations that protect ongoing investigatory matters from public disclosure. Despite these necessary and useful limitations, we are confident that effective cooperation can occur.

Question 5.	What does the FDA believe can be done to bring state-licensing authorities more actively into the battle against medical fraud and quackery?

Answer

More involvement of State licensing officials in battling health fraud is largely a function of resources. Most State agencies have very limited resources and a large mandate. Current economic crisis in many States exacerbate the recognized need for vigorous enforcement of States healing art laws. We have a long and effective involvement with State Boards of Pharmacy and with some medical licensing groups. We view the newly-formed NAAG/AFDO work group as an effective method to refer potential actions to licensing agencies. FDA has and will continue to provide testimony, affidavits and other support to those actions.

Question 6.	More and more, medical and financial records are being stored electronically on computers thus eliminating the traditional paper-trail that has been useful in previous fraud and quackery investigations. What steps is the FDA currently taking to meet the challenge of electronic record keeping in its investigations?

Answer

Computerized records are a regular part of the records reviewed by FDA inspectors during investigations. For several years, we have been acquiring computerized training and experience in a wide range of FDA regulated products. We have established Regional Computer Centers and Developed specialized systems that interface with other agencies such as U.S. Customs. The computer is now a routine part of what Agency investigators review during inspections.

Question 7.	Finally, according to written testimony that FDA submitted for Mr. Johnson, the FDA has established a toll-free telephone line to "further combat medical fraud." The line's purpose, said Mr. Johnson, is to "allow callers to ask medical staff [at FDA] about questionable promotional activities and practices or alert us [FDA] to healthcare products that may require FDA regulatory attention."

In an effort to verify the utility of this program, Regulation subcommittee staff -- without identifying themselves -- called the FDA's toll-free medical quackery hotline (1-800-238-7332) on April 8, 1992, to inquire about a medical promotion the Subcommittee on Regulation had received in the mail. Staff asked the FDA about the marketing and use of a medical device called a "cosmetic laser." This device is currently being marketed by The International Society of Cosmetic Laser Surgeons, Inc., located in Hermosa Beach, California. (See attached letter for a description of the product in question.) FDA hotline staff was confused both about how to process the request for information and how to proceed. Regulation Subcommittee staff was passed on to four different FDA officials -- none of whom could provide any helpful information. Finally, staff was put in contact with a Mr. Purvis. Mr. Purvis told my staff he was vaguely familiar with the device mentioned, but that the FDA has "nothing to do at all with the practice of medicine," and probably would not be the best place to find out about specific information about this company or its device. He suggested calling local medical societies for more information on the use of the cosmetic laser.

As a result of inquiry, questions now exist as to the utility of the Hotline. Please provide the subcommittees with additional information about the Hotline's mission, its operating procedures, and any steps that the Agency plans to take to streamline the process and thereby give Hotline users a greater sense that their questions are being answered and their concerns addressed.

Answer

The purpose of the Medical Advertising Hotline is to answer questions from health professionals, i.e., physicians, dentist, pharmacists, etc., regarding promotional activities by drug and device manufacturers. An FDA talk paper that outlines the purpose and nature of this hotline is attached.

The activities intended to be addressed by this information source were geared toward drug and device promotion with regard to product approval and labeling. This is different than practices understood as "quackery". The utility of the hotline can be estimated by looking at the activity reports (Attached). As the activity has increased, the staffing of this hotline has been accommodated by using medical staff personnel as well as specialists assigned on detail from the specific purpose of answering the hotline.

All calls received are logged in by the answering staff member. The enclosed log sheet for the anonymous call from a member of the subcommittee staff is attached. The format of the log sheet outlines the procedure that is followed when answering this line.

In the case of the April 8 call, although it did not involve a health professional and it did not appear to involve a drug, device or biologic, it was referred to the Division of Drug Marketing, Advertising and Communication (HFD-240). Mr. William Purvis, who is on the division staff, correctly identified the questionable activity as involving medical education and medical practice and not the sale or distribution of a drug, device or biologic. In properly identifying the activity, he appropriately referred the consumer to the State regulatory agency for medical practice. If three or four persons in Drug Advertising were involved in this call, it may have been due to the unusual nature of the call and the information requested. The question appears to have been answered properly.

3 Attachments

April 13, 1992

STRATEGY DOCUMENT
FOR
NATIONAL HEALTH FRAUD UNIT

Purpose

Establish a centralized process for targeting and coordinating regulatory activities and the dissemination of information combating health fraud.

Objective

Centralize information and coordination of health fraud activities.

Background

Health fraud, the promotion of false or unproven products is a large and complex problem. Each year millions of Americans risk their health as well as suffer economic loss as a result of health fraud. In an effort to combat this problem the Agency established in May 1988 the National Health Fraud Unit in the Kansas City district office.

The National Health Fraud Unit was charged with the following:

* To prepare a quarterly report summarizing all of FDA's actions against health fraud.

* To coordinate the federal/state/local government and private sector exchange of complaints and information involving health fraud.

* To work closely with other FDA components to facilitate public information and education campaigns.

* To facilitate communication with interested public health professionals and regulatory officials.

* To provide a central repository for FDA health fraud information and establish a system to allow Agency-wide access to that information.

A computerized data base was established, known as the Health Fraud Information System. It is accessible to all FDA field offices including District Health Fraud Coordinators, AIDS Coordinators, Public Affairs Specialists and Investigation and Compliance Branches. This staff received good cooperation from FDA components and other non-FDA groups, but it become apparent that locating this staff in headquarters would facilitate improved communication in the fight against health fraud. This is of particular importance because our activities in this area will need to increase as a result of the Commissioner's interest in combating the problem.

The Health Fraud Unit in Kansas city has performed efficiently within the limitations placed upon it. It was staffed with a technician who worked full time on data entry and by a compliance officer and public affairs specialist working in the unit on a part-time basis. It functioned primarily as a repository for health fraud information with limited proactive efforts or outreach capabilities. Its' geographic location may have hindered interaction within and outside the Agency. It was also hampered by compliance programs and instructions that need updating and uniformity in that the receipt of health fraud reports and information was on a random basis from the field, headquarters, centers and state and local governments. For these reasons and also due in part to a lack of resources, this health fraud unit lacked the focus to become a national health fraud coordinating and enforcement operation.

It has been decided that the Health Fraud Unit will be relocated in the Office of Regional Operations/Division of Federal-State Relations because of its interaction with state and local organizations which have expressed an interest in health fraud. (e.g., National Association of Attorneys General - NAAG, Association of Food and Drug Officials - AFDO)

Proposed Strategy

The Division of Federal-State Relations, within the Office of Regional Operations, will provide a central focus of information and coordination between ORA, field, headquarter units, the Centers, OGC and state officials. A health fraud working group consisting of representatives from each of these groups has been established and will meet on a scheduled basis to facilitate regulatory activities and information exchange.

For regulatory actions, NAAG and AFDO have established working groups of regulatory officials to coordinate pursuing specific health fraud targets with FDA. The Centers will continue to interact with FDA field offices in addressing targeted health fraud actions.

The Centers and field offices, as well as NAAG and AFDO, will provide DFSR proposed targets for joint or mutually assisted action on a regular basis. The Centers will designate a contact person to provide the targets for which they will support appropriate actions.

DFSR will provide the target list to the NAAG/AFDO committee and seek a listing of states interested in joint or mutually assisted actions. DFSR will then contact the field offices where the states are located and provide the necessary information for joint efforts. DFSR will coordinate field activities through the district Health Fraud Coordinators.

FDA field offices will provide day to day interaction with the Centers and state officials in the design and execution of investigations and regulatory actions and keep DFSR advised of progress. When action is taken by a state it will be requested to inform the district office who in turn will notify DFSR. DFSR will enter progress information into the Health Fraud Information System so that the system is current and national coordination can be accomplished. If and when a press release is issued on a targeted assignment the state will be encouraged to include FDA in the statement and FDA will likewise reference the state's coordination.

In addition to coordinating regulatory activities, DFSR will collect and enter into the Health Fraud Information System reports of suspected health fraud from both Agency and outside sources. This information will be used to produce periodic reports of health fraud activities and trends for Agency and external use. This outreach function will have a dual purpose. It will provide for the dissemination of health fraud intelligence data that can be used by intramural and extramural sources in the development of press releases, talk papers and educational and informational materials. By establishing a distribution network of health fraud contacts, the DFSR outreach effort will also serve as a mechanism for information exchange and project feedback.

It is important to maintain DFSR interaction with the district Health Fraud Coordinators, who will be primary contact points for the field. It will also be necessary to coordinate all AIDS fraud activities with the AIDS Coordinators at the field and headquarters level. Extramurally, in addition to AFDO and NAAG, DFSR will coordinate our outreach effort with the US Postal Service, Federal Trade Commission and other government agencies and private health fraud organizations.

Project Needs

Relocation of the National Health Fraud Unit to DFSR will necessitate the following;

- Immediate acquisition of a Consumer Safety Technician, to maintain the health fraud data base and a Consumer Safety Officer, to manage the day-to-day operations of the unit.
- Updating and consolidation of all field and management directives dealing with health fraud to provide Agency personnel with background on the relocation of health fraud data collection/compliation responsibilities, reaffirmation of the importance of this initiative and highlighting highlight the revised reporting requirements to DFSR.
- Identification of and contact with all potential sources of health fraud information so that the data base is contemporary and comprehensive.

- o Development of an intramural and extramural coordination network including establishment of a working group comprised of representatives from the Centers, the Offices of Health Affairs, Consumer Affairs and Public Affairs, the Office of Regulatory Affairs, the field Health Fraud Coordinators, NAAG and AFDO and other governmental and private organizations.

- o Regularly schedule meetings to coordinate regulatory actions and information exchange. It is anticipated that this expanded outreach function, in conjunction with the assimilation of the Agency's AIDS fraud activities, may require an additional FTE for the Health Fraud Unit.

- o Aquisition of additional operating dollars for organizing meetings, travel and publications costs associated with the coordination effort and to purchase extra health fraud data bases such as those of the Consumer Health Information Research Institute and the National Council Against Health Fraud.

The Health Fraud Information System should be fully operational within three months and the coordination effort fully functional within a year.

for Ronald G. Chesemore, Associate Commissioner for Regulatory Affairs (HFC-1)

Concur ____________ Nonconcur ____________ Date 4/28/92

Gerald E. Vince, Director, Office of Regional Operations (HFC-100)

Concur ____________ Nonconcur ____________ Date 4/19/92

Heinz G. Wilms, Director, Division of Federal-State Relations (HFC-150)

Concur ____________ Nonconcur ____________ Date [illegible]

TALK PAPER

FOOD AND DRUG ADMINISTRATION
U.S. Department of Health and Human Services
Public Health Service 5600 Fishers Lane Rockville, Maryland 20857

FDA Talk Papers are prepared by the Press Office to guide FDA personnel in responding with consistency and accuracy to questions from the public on subjects of current interest. Talk Papers are subject to change as more information becomes available. Talk Papers are not intended for general distribution outside FDA, but all information in them is public, and full texts are releasable upon request.

T91-53
Sept. 12, ,1991

Mike Shaffer
(301) 443-3285

FDA TOLL-FREE PHONE LINE FOR HEALTH PROFESSIONALS

FDA's toll-free telephone service set up for health professionals is scheduled to begin September 16. Physicians, pharmacists, nurses and veterinarians as well as other health professionals can use it to ask questions about the agency's policies on medical advertising, marketing and promotion and for discussing promotional activities and practices for health care products that may require FDA attention.

The main number is 1 800 AD-US-FDA (1 800 238-7332).

The service is designed to cover issues involving drugs, biologicals, medical devices and veterinary products.

When appropriate, FDA will refer calls to outside medical, industry and trade organizations who have agreed to accept them. Interest in FDA's advertising and promotion policies has increased following publication of an article by Commissioner David A. Kessler, M.D., in the July 18 New England Journal of Medicine (see Talk Paper T91-40, July 18, 1991) and an earlier article by Dr. Kessler in the Journal of the American Medical Association November 14, 1990.

-MORE-

The two 800 number lines will be answered by the Medicine Staff in FDA's Office of Health Affairs during normal business hours. Automatic answering equipment allows callers to record requests for information or leave messages at other times. A telecopier (FAX) will permit the transmission of documents during and after business hours. The FAX number is 1 800 3443-FDA (1 800 344-3332).

####

May 19, 1992

Food And Drug Administration Medical Advertising Line
Office of Health Affairs, Medicine Staff

Summary of Calls
September 19, 1991 through May 8, 1992

- The FDA Medical Advertising Line is currently in its 36th week of operation. As of May 8, 1992 a total of 1,736 calls have been received by Medicine staff. These include calls that were received via telephone and answering machine. These data are in a Paradox file which was created in order to conduct an evaluation of Advertising Line calls for the first six months of operation. This data base also contains call data through May 8, 1992.

- A total of 39 calls were received during the week ending May 8th (the 34th week of operation), an 86 percent increase over the previous week's total(See Figure 1).

- The number of calls per week has leveled off to an average of 32 calls per week for the past 6 week period (See Figure 1).

- In direct correlation, the number of calls per day has also leveled off to an average of 6 calls per day for the past 6 week period (See Figure 2).

- Advertising and marketing complaints comprised 10 percent of all calls made during the 34th week of operation. The 32nd week of operation had the largest percentage of advertising calls for the last six week period(See Figure 3).

- The percentage of teeth whitener calls has dropped drastically during the past 6 weeks, accounting for an average of less than 4 percent of all calls per week(See Figure 4).

- During the past month pharmacists made the largest number of calls(30 percent) followed by physicians and dentists with 26 percent. Other health care professionals ranked third with 13 percent(See Figure 5). Veterinarians made the least number of calls, accounting for only 2 percent of all calls.

- Since April 29 a total of 17 medication errors were reported on the toll free line. This consisted of actual medical errors and situations where a medication error could occur. Fifty nine percent of these calls were from physicians, while 41 percent were from pharmacists(See Figure 6).

- The types of medical errors reported for actual and hypothetical instances are displayed in Figure 7. (Since a medication error can have multiple types, the total number of categories exceeds the total number of errors.) One third of all medication type errors were attributable to pharmacists who filled prescriptions incorrectly, while nearly a quarter of medication errors were due to labeling or sound alike names, respectively. The remaining errors were due to an incorrect prescription being written or confusion over the same dosage.

- Sixty five percent of all medication errors reported actually occurred, while the rest were situations where an error could occur in the future. Out of a total of 11 actual errors, nearly three fourths were made by pharmacists, 18 percent by physicians, and 9 percent by nurses(See Figure 8).

- Actual instances of medication errors consisted of: 1) incorrectly filled prescriptions, 2) incorrectly written prescriptions, 3) confusion caused by labeling that looks the same, and 4) confusion caused by equivalent dosages. These data are depicted in Figure 9.

TOTAL NUMBER OF CALLS PER WEEK

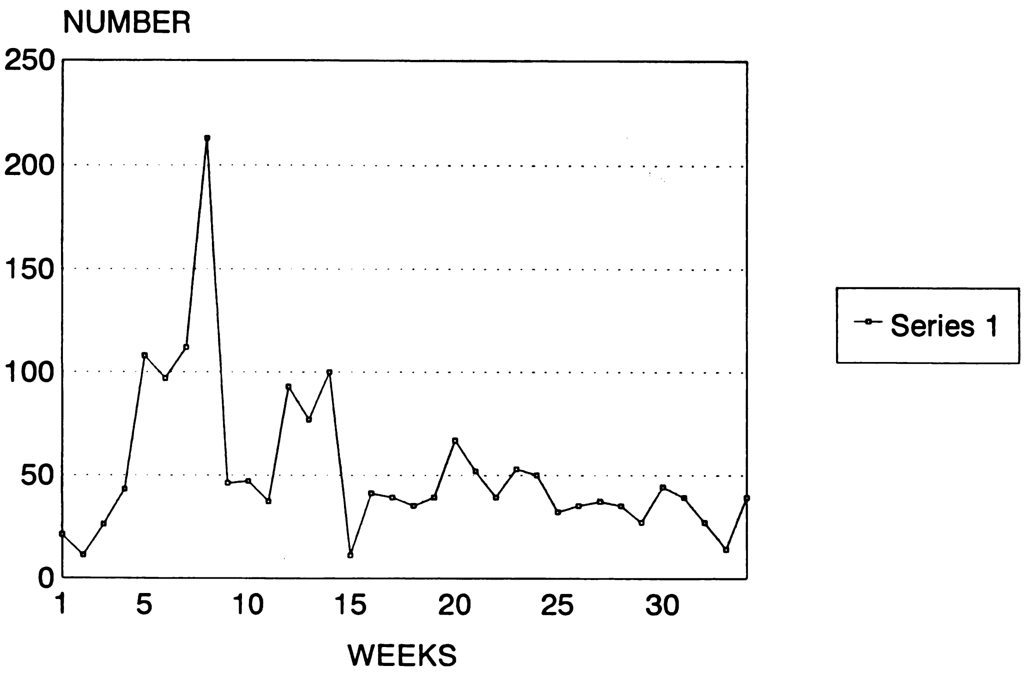


Figure 1

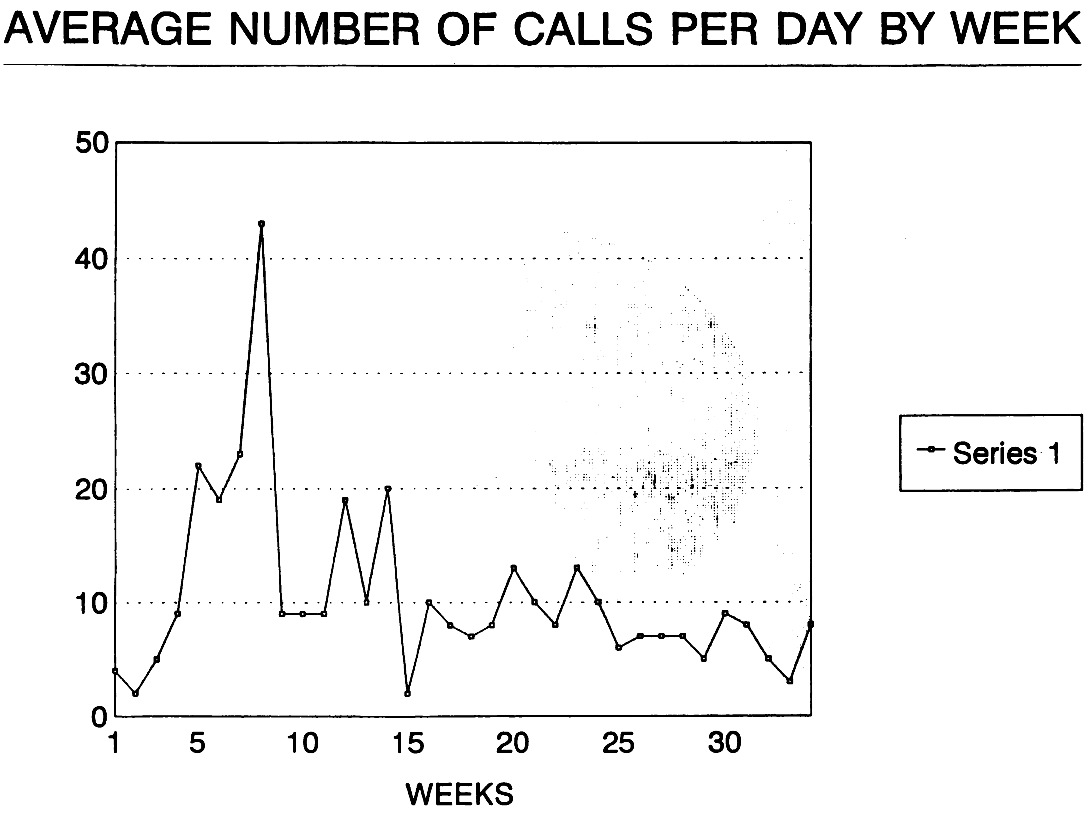

AVERAGE NUMBER OF CALLS PER DAY BY WEEK

Figure 2

ADVERTISING AND MARKETING COMPLAINTS AS A PERCENTAGE OF TOTAL CALLS

29TH - 34TH WEEKS OF OPERATION

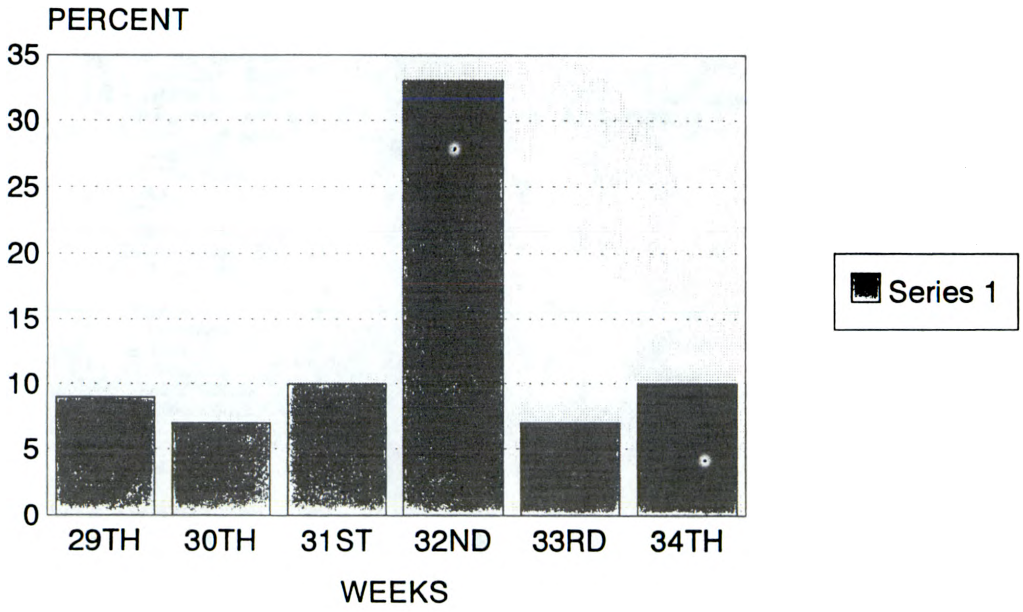
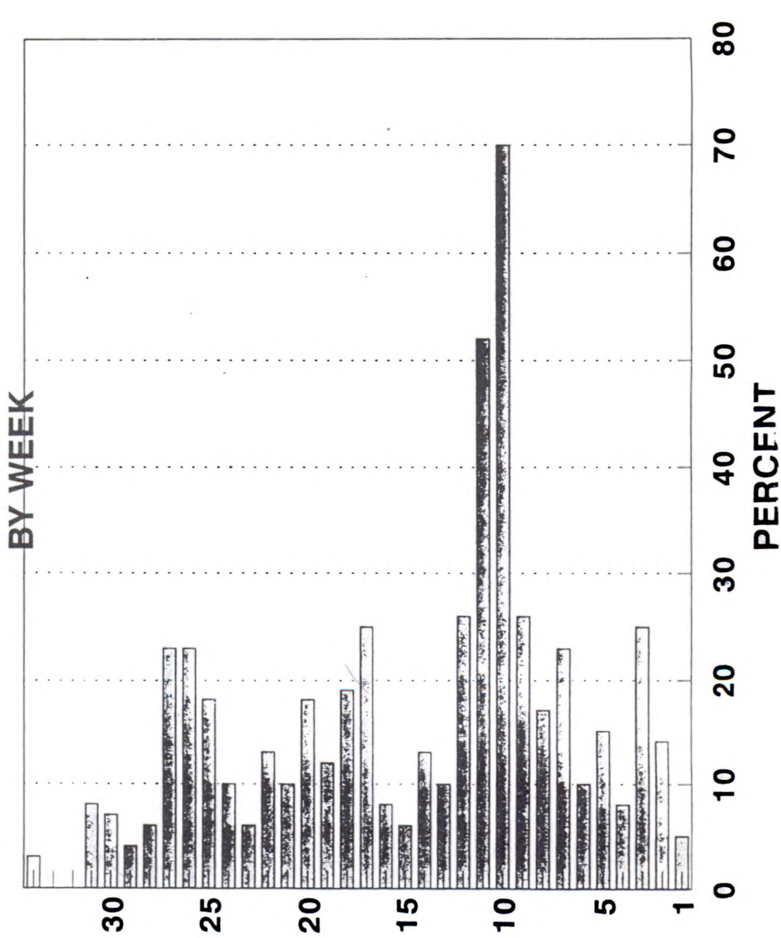


Figure 3

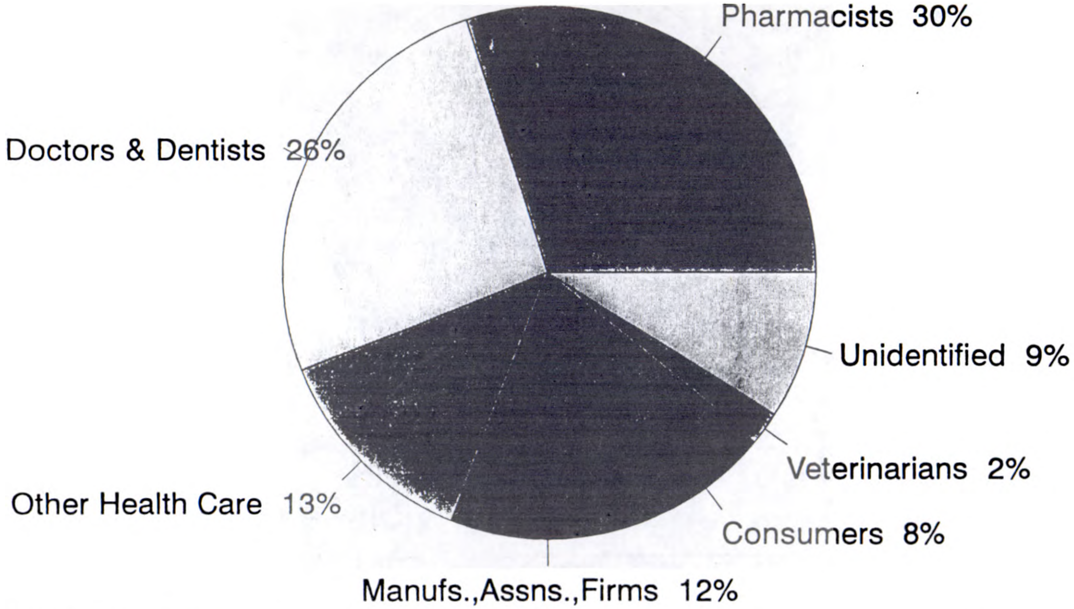


TEETH WHITENERS AS A PERCENTAGE OF TOTAL CALLS

BY WEEK

PERCENT OF CALLS BY PROFESSION

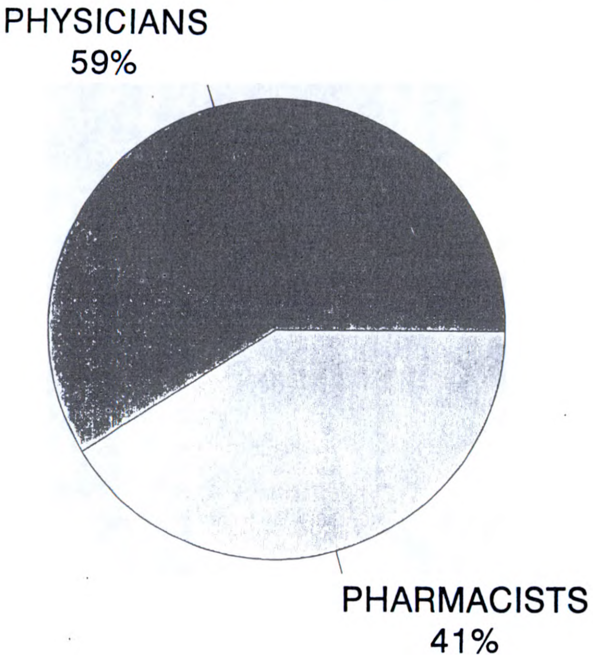
FOR THE 31ST THROUGH THE 34TH WEEK OF OPERATION



* Includes Other Health Care Profesionals & Unclassified

N = 120

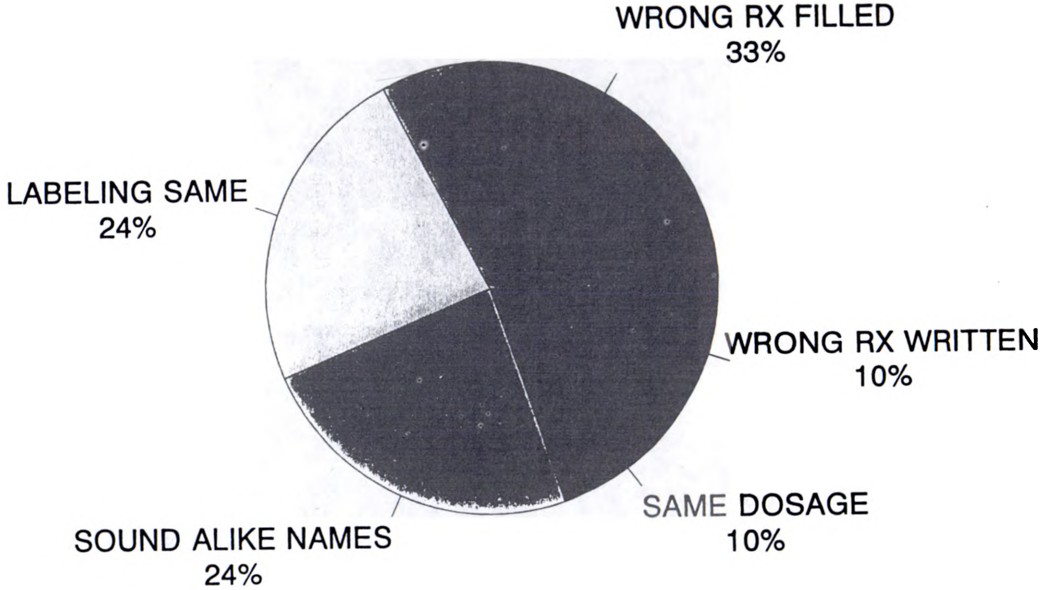
PERCENT OF MEDICATION ERROR CALLS BY PROFESSION OF CALLER; APRIL 29 - MAY 15, 1992



N = 17

Figure 6

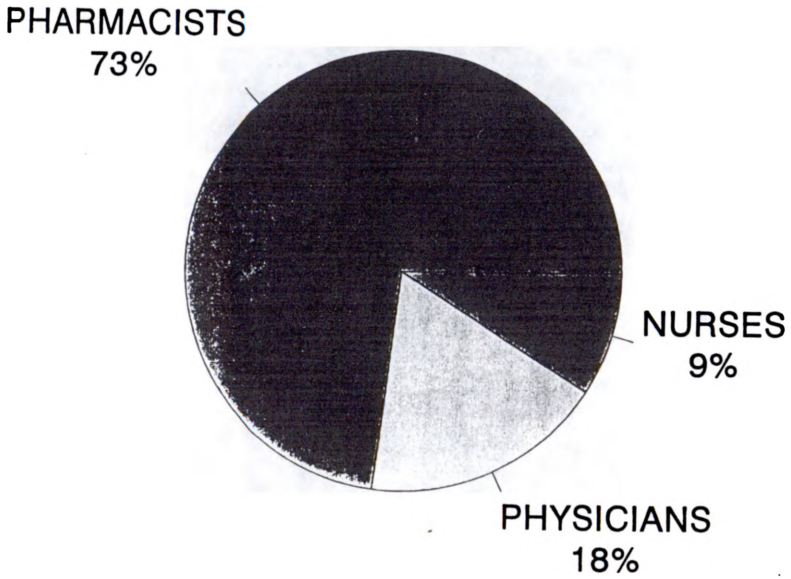
TYPES OF MEDICAL ERRORS REPORTED FOR ACTUAL AND HYPOTHETICAL INSTANCES



CATEGORIES ARE NOT MUTUALLY EXCLUSIVE; N = 21

Figure 7

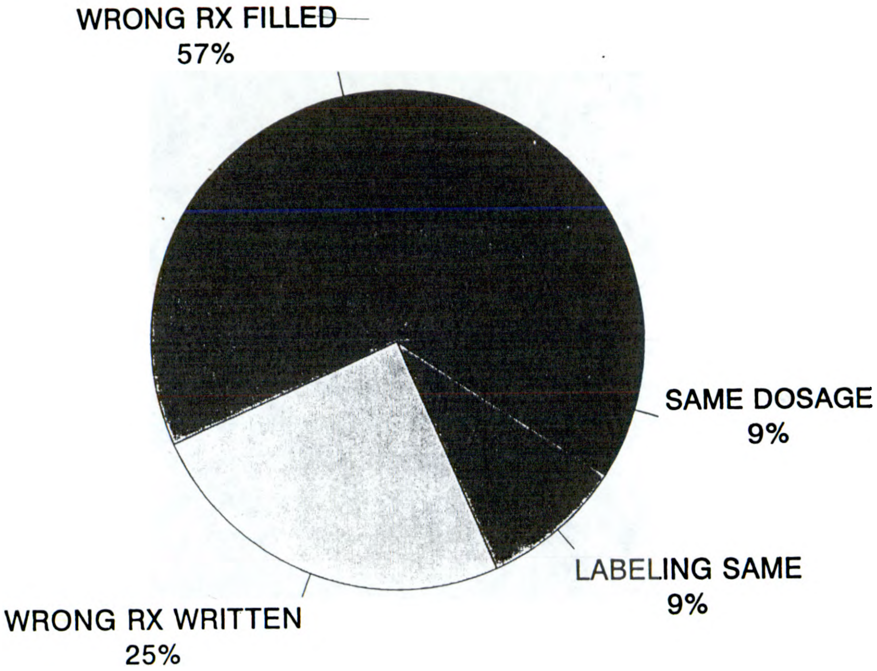
PERCENT OF ACTUAL MEDICATION ERRORS BY PROFESSION; APRIL 29 - MAY 15, 1992



N = 11

Figure 8

TYPES OF MEDICAL ERRORS REPORTED FOR ACTUAL INSTANCES



N = 11

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